FIBRE FORTIFICATION TO INCREASE STOOL FREQUENCY IN CHILDREN WITH A HISTORY OF CONSTIPATION

A Thesis Submitted to the College of Graduate Studies and Research
In Partial Fulfillment of the Requirements
For the Degree of Master of Science
In the College of Pharmacy and Nutrition
University of Saskatchewan
Saskatoon, Saskatchewan, Canada

By
Carla Flogan, RD

PERMISSION TO USE

In presenting this thesis in partial fulfillment of the requirements for a Postgraduate degree from the University of Saskatchewan, I, Carla Flogan, agree that the Libraries of this university may make this thesis available for inspection. I further agree that permission to copy this thesis in whole or in part for scholarly purposes may be granted by the supervisor of my thesis work or, in her absence, the Head of the Department or the Dean of the College in which my thesis was completed. It is understood that any copying, publication or use of any part of this thesis for financial gain shall not be allowed without my written permission. It is also understood that due recognition shall be given to me and to the University of Saskatchewan in any scholarly use of the material contained in my thesis.

Requests for permission to copy or to otherwise make use of the material in this thesis in whole or in part should be addressed to:

Dean of the College of Pharmacy and Nutrition
110 Science Place
University of Saskatchewan
Saskatoon, Saskatchewan, Canada
S7N 5C9

ABSTRACT

Constipation is a serious problem in the pediatric population and often requires medical management with laxatives and enemas. Participants (2-10 years of age, n=13) with a history of mild constipation were assigned randomly to a fibre treatment or placebo group. After three weeks, subjects were crossed over to the other treatment. Pea hull fibre (4.0-7.6 g/day = 3.6-6.8 g/day of dietary fibre) was added to snack foods and an inulin supplement (5.0 g/day = 4.5 g/day of dietary fibre) was given, whereas the placebos were non-fortified snacks and maltodextrin (5.0 g/day).

Subjects or their parents documented stool frequency, stool consistency, occurrence of abdominal pain and intake of snack foods and the supplement. Over the final two weeks, there was a trend towards an increase in the mean number of daily bowel movements in the fibre treatment group compared to the placebo group (n=11, 0.68 ± 0.18 vs. 0.59 ± 0.26, p=0.064). Exclusion of one subject with diarrhea-type stools led to a significant difference between groups (n=10, 0.54 ± 0.18 vs. 0.67 ± 0.22, p=0.002). Stool consistency, using the Bristol Stool Form Rating Scale, showed no significant differences in stool consistency between groups (p=0.379) nor was there a difference in the incidences of abdominal pain (p=0.129). Not all subjects experienced abdominal pain. The inulin supplement (91% compliance rate; 1 serving per day) was consumed more consistently than were the snack foods fortified with pea hull fibre (77% compliance rate; 2 servings per day). There were no significant differences in the intake of the snacks or supplement when the placebo and treatment groups were compared. Energy intake was significantly lower during the fibre treatment period compared to placebo (n=12, 1307 ± 296 kcal/day vs. 1441 ± 285 kcal/day, p=0.035).

The addition of pea hull fibre to typical snack foods and an inulin supplement to beverages were well accepted by children and no adverse effects were reported. Fibre fortification of snack foods with pea hull fibre and fibre supplementation of beverages with inulin may provide an alternative means to treat pediatric constipation.

ACKNOWLEDGEMENTS

I would like to thank everyone who has contributed to the completion of this thesis, both mentors and supporters. I feel very fortunate to have achieved this milestone in my career!

I would like to extend my gratitude to my supervisor Dr. Wendy Dahl. You have been a great source of ideas and inspiration, as well as support for this endeavour. Thanks for sticking with me through all of the ups and downs life has to offer.

I would also like to thank the members of my advisory committee, Dr. Robert Tyler, Dr. Susan Whiting and Dr. Carol Henry. Your time, guidance and expertise were greatly appreciated.

To the other graduate students in the College of Pharmacy and Nutrition, especially Lindsay Tumback, I would like to say thank you for your support and dedication, as well as for serving as a source of motivation.

I would like to extend my sincere gratitude to the College of Pharmacy and Nutrition, the College of Graduate Studies and Research, and Saskatchewan Pulse Growers for providing financial support and allowing me to pursue this research project. I would also like to thank colleagues within the Saskatoon Health Region who were willing to work around my class schedule.

Finally, I am very grateful to my husband Eric for all of his love and support during this busy time. I couldn't have done this without you – thanks for making supper and weighing inulin during the crunch times. My family has also been a great source of support, for which I am thankful.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

ABBREVIATIONS

ACGCC	American College of Gastroenterology Chronic Constipation
AI	Adequate intake
AOAC	Association of Official Analytical Chemists International
CFIA	Canadian Food Inspection Agency
CMA	Cow's milk allergy
CMP	Cow's milk protein
CSFII	Continuing Survey of Food Intakes by Individuals
CTT	Colonic transit time
DP	Degrees of polymerization
DRI	Dietary Reference Intakes
FOS	Fructooligosaccharides
HAPC	High amplitude propagating contractions
IOM	Institute of Medicine
NASPHGAN	North American Society for Pediatric Gastroenterology, Hepatology & Nutrition
NHANES	National Health and Nutrition Examination Survey
PACCT	Paris Consensus on Childhood Constipation Terminology
PedsQL™	Pediatric Quality of Life Inventory
QOL	Quality of life
RDA	Recommended Dietary Allowance
SCFA	Short chain fatty acids
scFOS	Short chain fructooligosaccharides
STC	Slow transit constipation
UL	Tolerable Upper Intake Level
USDA	United States Department of Agriculture
WGTT	Whole gut transit time

CHAPTER 1
INTRODUCTION

1.1 BACKGROUND

Most children do not consume an adequate amount of dietary fibre on a regular basis, regardless of the recommendation used for assessment (Nicklas, Farris, Myers, & Berenson, 1995; Saldanha, 1995; Hampl, Betts, & Benes, 1998; Monge-Rojas, & Rivas, 2001; Kranz, Mitchell, Siega-Riz, & Smiciklas-Wright, 2005). Studies have shown that there is a link between low dietary fibre intake and constipation in children (Roma, Adamidis, Nikolara, Constantopoulos, & Messaritakis, 1999; Morais, Vitolo, Aguirre, & Fagundes-Neto, 1999; Ip, Lee, Chan, & Young, 2005). In addition to its laxation properties, dietary fibre has many health benefits, which are associated with higher intakes (Martlett, McBurney, Slavin, & American Dietetic Association, 2002; Kranz *et al*, 2005; Slavin, 2008).

Historically, guidelines for dietary fibre intake in children have erred on the side of caution. It was thought that high amounts of dietary fibre would result in nutrient imbalances (McClung, Boyne, & Heitlinger, 1995). For example, phytates tend to bind minerals thereby reducing their bioavailability (Williams, 2006). However, previous research has not indicated support for this belief (McClung *et al*, 1995). Also, there has been concern that energy intake could be reduced (Williams, 2006); however, this may

be considered a benefit in the context of the current epidemic of pediatric obesity, which is becoming a concern even in developing countries.

Traditional and a select number of novel sources of dietary fibre have been approved by the Canadian Food Inspection Agency for addition to regular foods. Two such fibre sources are pea hull fibre and inulin and both are approved for labeling purposes in Canada. Pea hull fibre has properties similar to those of refined wheat flour in terms of taste and texture, but has the added advantage of providing a significant amount of insoluble fibre. It can be used in many applications such as extruded cereals, pancakes, cookies, crackers and cereal bars. Inulin, a prebiotic, can be added to beverages such as yogurt drinks. Inulin is currently used in many food applications, primarily as a fat/sugar replacement or as a texture modifier.

The use of both inulin and pea hull fibre would provide a two-pronged approach to improving constipation: pea hull fibre has proven laxation properties, whereas inulin promotes intestinal health with its own inherent overall health benefits. The intent was to mimic a regular diet, as most foods contain both soluble and insoluble fibre.

Research in adult women has shown that dietary fibre intake is commonly 2:1, insoluble: soluble fibre (McEligot *et al*, 2002). In Brazilian children 4-14 years of age, it was found that the intake of dietary fibre for all subjects was in the range of 1.4-1.5:1, insoluble: soluble, regardless of frequency of bowel movements or level of dietary fibre intake (Paulo, Amancio, Morais, & Tabacow, 2006). The addition of either type of fibre (in supplement form) to a regular diet has been seen to be well-tolerated by children experiencing constipation (Castillejo, Bullo, Anguera, Escribano, & Salas-Saluado, 2006; Loening-Baucke, Miele, & Staiano, 2004).

1.2 PURPOSE OF THE STUDY

The purpose of this study was to determine the effects of consumption of snacks fortified with pea hull fibre and beverages supplemented with inulin on the bowel habits of children with a history of constipation. To evaluate this, quantitative data on bowel movement frequency and consistency, as well as data on discomfort during the fibre treatment and placebo periods, were collected.

1.3 OBJECTIVES

This study will seek to achieve the following objectives:

1. To determine the acceptance by children of foods fortified with pea hull fibre or inulin.
2. To determine the effect of the consumption of foods fortified with pea hull fibre or inulin on the stool patterns and abdominal discomfort of children with a history of constipation.
3. To determine if the consumption of foods fortified with pea hull fibre or inulin would help children achieve the recommended Adequate Intake for dietary fibre.

1.4 HYPOTHESES

Whereas fibre supplements have been investigated in children, to our knowledge no research has examined the addition of fibre to foods regularly consumed by children. Research on the effects of fibre-fortified food in children is currently lacking.

Our hypothesis is that the consumption of foods fortified with pea hull fibre (cereal bars, crackers, snack cakes and cookies) and beverages supplemented with

inulin will significantly increase dietary fibre intake in children with a history of mild to moderate constipation. We further hypothesize that an increased fibre intake will increase stool frequency, improve stool consistency and decrease abdominal discomfort in these children.

1.5 SIGNIFICANCE OF THE STUDY

It is difficult to provide dietary counseling regarding high fibre diets due to a lack of commercially available and acceptable high fibre food products for children. Fibre fortification provides a means to increase fibre intake of children without having to make drastic changes to eating habits, which is often challenging. Research into the various types of dietary fibre has uncovered a whole host of beneficial physiological effects in humans. Because of this, one of the current consumer trends is an increase in the interest in high-fibre foods that are appealing and taste good, which is demonstrated by the increased number of high-fibre snack foods available on store shelves.

A low dietary fibre intake (Kimm, 1995) and constipation (Pashankar & Loening-Baucke, 2005; Misra, Lee, & Gensel, 2006) have also been linked to obesity in children. There may be advantages in this population for weight control due to the indigestibility of dietary fibre, in addition to laxation and intestinal health benefits.

This study was intended to demonstrate the benefits of adding sources of fibre to everyday foods and beverages in order to maximize the benefits that various types of dietary fibre can provide. The majority of children in the general population consume inadequate amounts of dietary fibre from a diet low in plant foods and high in refined

foods. This study also was intended to demonstrate that high-fibre foods can be made appealing and desirable to children.

1.6 SUMMARY

Low intakes of dietary fibre appear to be linked to constipation in childhood. Fibre fortification of snack foods and fibre supplementation of beverages may be beneficial for treating constipation. This study examined the effects of fibre fortification and supplementation on the bowel habits of constipated children, and on intakes of dietary fibre and energy.

CHAPTER 2
LITERATURE REVIEW

2.1 INTRODUCTION

The normal range of bowel movements varies from individual to individual and can depend on age, type of food intake, medications, illness, and developmental and psychosocial factors (Coughlin, 2003). It is a widely held belief that most cases of constipation have no apparent organic cause (Youssef & Di Lorenzo, 2001), and this is often termed functional or idiopathic constipation. However, new research is suggesting that slow colonic transit time may account for some cases of so-called "functional" constipation (Southwell, King, & Hutson, 2005). Slow transit time is thought to occur as a result of colonic dysmotility (Hutson, McNamara, Gibb, & Shin, 2001; Southwell *et al*, 2005), although there is some controversy around this (Sherrington & Forbes, 2005). It has been classified as a type of constipation since new techniques have become available for its diagnosis (Southwell *et al*, 2005).

The characteristics of childhood constipation are different from those of adults. Youssef and Di Lorenzo (2001) highlight some of these important differences, such as that pediatric constipation is more common in males than in females, whereas the opposite is true in adults. Also, children tend to withhold stool as a common behaviour, whereas adults have more "straining" behaviours (Youssef & Di Lorenzo, 2001). With this withholding behaviour, soiling (sometimes called encopresis) occurs when stool

accumulates in the rectum and liquid stool starts to seep around the impaction (Youssef & Di Lorenzo, 2001).

Health professionals often counsel a "high fibre diet" along with increased fluid and physical activity with families of children with constipation concerns. These recommendations are based more on tradition than on evidence-based medicine. However, some research has shown a role for dietary fibre in the management of constipation in children (Castijello *et al*, 2006; Loening-Baucke *et al*, 2004). Clarification is required as to who will benefit from what (e.g. dietary fibre, probiotics, prebiotics, osmotic laxative or lubricant), how much (daily or as needed) and for how long (prevention versus maintenance). Some information is available in the literature; however, more research is required to answer each of these questions.

2.2 DIETARY FIBRE

2.2.1 General Health Benefits

There is much debate about the definition of dietary fibre and the methodology used for its analysis, as well as the benefits and risks associated with its consumption. The consumption of dietary fibre is associated with a number of health benefits (Martlett *et al*, 2002). It is known to aid in normal laxation and may be beneficial in the prevention of several disease states. Epidemiology has shown that fibre has a role in the prevention of cardiovascular disease, hypertension, stroke, obesity, some cancers and type 2 diabetes (Martlett *et al*, 2002; Slavin, 2008). Soluble fibre, in particular, is known to have a cholesterol-lowering effect (Hunt, 1993). Recently, other properties of

fibre, such as fermentability and viscosity, have emerged as potential properties which contribute beneficial physiological effects (Slavin, 2008).

One of the challenges of studying the health benefits of fibre is that it is difficult to separate out the effects of fibre from the numerous other substances found in foods. Therefore, there is potential for a synergistic relationship between fibre and the other components, for example phytochemicals, found in fibre-containing foods that may contribute to its beneficial effects (IOM, 2002). For this reason, it is generally recommended to consume fibre from food sources, as opposed to supplements, with the exception of some therapeutic circumstances (Martlett *et al*, 2002). This will serve to ensure that all of the potentially helpful components are being consumed.

Some fibre sources are recognized to produce laxation in a healthy population. Examples include cereal brans, psyllium and methylcellulose, which are sometimes commercially available as supplements (Slavin, 2008). A common effect observed with all of these fibre sources is an increase in stool weight, which occurs as a result of the fibre in the colon, by the water-holding abilities of the fibre and by the fermentation of the fibre by resident bacteria (Slavin, 2008).

2.2.2 Definitions

The Standing Committee on the Scientific Evaluation of Dietary Reference Intakes assembled a Panel on the Definition of Dietary Fibre to propose a definition for international use (see Table 2.1) (IOM, 2002).

Table 2.1 Definitions of Dietary Fibre

Type of Fibre	Definition	Examples
Dietary Fibre	Consists of nondigestible carbohydrates and lignin that are intrinsic and intact in plants.	Cereal brans, resistant starch (e.g. flaked corn cereal), raffinose, stachyose and verbacose in legumes, fructans in foods
Functional Fibre	Consists of isolated, nondigestible carbohydrates that have beneficial physiological effects in humans, typically added to other foods.	Manufactured resistant starch, isolated oligosaccharides such as inulin or oligofructose, synthetically manufactured oligosaccharides, non-digestible animal carbohydrate (e.g. connective tissue)
Total Fibre	The sum of dietary fibre and functional fibre.	Both dietary fibre and functional fibre are considered in calculating total intake

Adapted from: IOM. (2002) *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients).*Washington, DC: National Academies Press.

It was deemed necessary to have two separate definitions to account for all types of dietary fibre such as the carbohydrate in plant cell walls and storage carbohydrates, carbohydrates from animal sources, and isolated or low molecular weight carbohydrates that are either natural or synthetic (IOM, 2002). Isolated fibres, such as inulin, are those that are manufactured from a natural food source.

Further to these definitions, specific characteristics (some identifiable using analytical methods) have been attributed to dietary fibre in order to differentiate it from functional fibre. Functional fibre includes carbohydrates not recovered by alcohol precipitation and nondigestible mono- and disaccharides and polyols (IOM, 2002). They must come from intact/naturally-occurring food sources only, and be resistant to human enzymes. Certain resistant starches that have some or all of these characteristics are also

considered to be dietary fibre (IOM, 2002). Functional fibres are chemically, enzymatically or aqueously isolated, which includes manufactured resistant starch.

The chemical properties of dietary fibre have been described as soluble or insoluble, which is based on analytical processing rather than physiological effects or composition (Dikeman & Fahey, 2006). This feature of fibre is problematic, as it is challenging to ascertain how the solubility of a fibre might behave differently in vivo compared to in vitro (Mongeau & Brooks, 2003). Also, methods for determining solubility vary and this can make it difficult to compare data from different countries. In the United States, regulation of dietary fibre is based on the analytical methods approved by the Association of Official Analytical Chemists International (Otten, Hellwig, & Meyers, 2006). In Canada, the Canadian Nutrient File (Health Canada, 2007) is the major source for nutrient information and it is based on the USDA database, so by consequence the AOAC methods generally describe the fibre content of foods in Canada.

Most fibre sources can be analyzed using the AOAC Method 985.29 (IOM, 2001). However, this methodology is not applicable to certain functional fibre sources including resistant starch, nondigestible oligosaccharides (fructo- and galacto-oligosaccharides) and polydextrose (Slavin, 2008). Methods for analyzing the fibre content of these fibre sources are in development (IOM, 2001).

2.2.3 Composition

Dietary fibre is found, for the most part, in plant-based foods. Dietary fibre is made up of carbohydrate and non-carbohydrate polymers (Mongeau & Brooks, 2003).

These are, generally speaking, the structural components of the plant. The carbohydrate polymers are often identified as nonstarch polysaccharides (NSP) in the literature. This serves to make the distinction between these and the starch components of plant-based foods.

Recently, certain starch components, termed "resistant starch", have been found to escape digestion in the small intestine and can be fermented in the colon, although there is some debate as to whether resistant starch is partially or completely fermented (Spiller, 1994; Tungland & Meyer, 2002). Examples of foods containing resistant starch include corn, potatoes, grains, bananas and legumes. The "resistance" to digestion of the starch in these foods tends to increase when the food is cooked and then cooled, for example when the amylose and/or amylopectin is retrograded (Spiller, 1994). It appears that the amylose molecule folds in on itself, rendering the α 1-4 bonds unavailable to α-amylase (Spiller, 1994).

In some cases, protein components of foods escape digestion and enter the colon, where they are fermented by the resident microflora in much the same manner as plant-based foods (Mongeau & Brooks, 2003). Examples of this would be connective tissue or chondroitin found in animal tissues (Tungland & Meyer, 2002).

2.2.4 Physiological Effects of Dietary Fibre

Dietary fibre and functional fibre are known to have a number of physiological effects along the gastrointestinal tract, including an effect on gastric emptying, satiety and fermentation (Hunt, 1993; IOM, 2001; Martlett *et al*, 2002; Spiller, 1994). These physiological effects are thought to play a role in the prevention of hyperlipidemia,

hypertension and coronary artery disease, as well as colorectal cancer, breast cancer, duodenal ulcer, constipation and laxation, and diverticular disease (Gray, 1995; Hunt, 1993; Martlett *et al*, 2002). It should be noted that the role of dietary fibre in colorectal cancer is controversial at present (Martlett *et al*, 2002; Slavin, 2008).

More recently, the physicochemical properties of fermentability and viscosity have been recognized as having beneficial physiological effects in humans. Fermentation occurs almost exclusively in the large intestine, as a result of dietary fibre escaping the small intestine. The degree of fermentation is variable and may be dependent upon the degree of polymerization, structural arrangement and solubility of the carbohydrate (Nyman, 2002).

Examples of highly fermentable fibre sources include arabinoxylans in cereal grains and pectin in fruits and vegetables (Rose, DeMeo, Keshavarzian, & Hamaker, 2007). When rapid fermentation occurs, the microflora are known to produce short chain fatty acids (SCFA) (Dikeman & Fahey, 2006). The SCFAs produced include butyrate, acetate and propionate, which are known to decrease the pH of the colon contents (Rose *et al*, 2007). In the context of bowel health, this has the effect of decreasing the proliferation of harmful bacteria (Rose *et al*, 2007). Furthermore, the production of butyrate provides a fuel source for epithelial cells of the large intestine with effects including a decrease in the inflammatory response (Rose *et al*, 2007).

More slowly or incompletely fermented fibres, on the other hand, stimulate laxation by increasing stool weight and decreasing colonic transit time (Rose *et al*, 2007; Dikeman & Fahey, 2006). These effects have the potential to increase fecal

output and the frequency of bowel movements (Rose *et al*, 2007). Non-fermentative fibre sources tend to increase the viscosity of the digesta (Malkki, 2001).

Examples of viscous fibres are gums, pectins, psyllium and β-glucans (Dikeman & Fahey, 2006). These fibres thicken when mixed with fluids and have been shown to influence blood cholesterol and glucose levels, delay gastric emptying, and decrease small intestine transit time (Malkki, 2001). The literature on viscous fibres, as with all types of dietary fibres, is difficult to interpret due to differences in terminology and definitions (Dikeman & Fahey, 2006).

2.2.5 Canadian Regulations

The Canadian Food Inspection Agency governs food labelling practices in Canada. This agency uses definitions for fibre recommended in 1985 by the Expert Advisory Committee on Dietary Fibre, reporting to Health Canada (see Table 2.2), which have some similarities with those presented by the IOM. They both include two main types of fibre, one of which is "naturally-occurring" sources (dietary fibre), whereas the other covers manufactured or isolated types of dietary fibre (functional or novel fibre).

Table 2.2: Types of Fibre as Defined by the Canadian Food Inspection Agency

Type of fibre	Definition	Composition	Examples
Dietary fibre	The endogenous components of plant material in the diet, which are resistant to digestion by enzymes produced by humans. They are predominantly non-starch polysaccharides and lignin.	The composition varies with the origin of the fibre and includes soluble and insoluble substances.	Fruits, nuts, legumes and cereals, when traditionally processed or prepared.
Novel fibre or novel source	A food that has been manufactured to be a source of dietary fibre, **and**: i) has not traditionally been used for human consumption to any significant extent; **or** ii) has been chemically processed (e.g., oxidized) or physically processed (e.g., very finely ground) so as to modify the properties of the fibre; **or** iii) that has been highly concentrated from its plant source.	It must be demonstrated that a novel fibre is safe and that it functions physiologically as dietary fibre for it to be considered a source of dietary fibre.	Apple pomace, oat hull fibre, pea hull fibre, psyllium seed husk, sugar beet fibre.

CFIA (2003). Retrieved from the Health Canada website on November 5, 2008: http://www.inspection.gc.ca/english/fssa/labeti/guide/ch6ae.shtml.

2.2.6 Guidelines in Children

There is some literature on the intake of fibre in children. No one single guideline would serve to encompass children of all ages and stages, due to the differences in their growth and development, as well as their energy requirements. One recommendation was proposed by the American Academy of Pediatrics Committee on Nutrition in 1993 and it was 0.5 g of dietary fibre per kilogram of body weight. However, this guideline never gained widespread use.

The most popular guideline, historically, is the one proposed by the American Health Foundation in 1995, which has become known as the "age plus 5 g" rule. For example, a 7 year old child should consume 12 g of dietary fibre daily (7 years old plus 5 g = 12 g/d). This guideline was based on the results of NHANES II (1976-1980), as well as other national surveys in the U.S. The average fibre consumption at the time was 12 g/d, ranging from 8-15 g/d in the various age/sex groups (National Center for Health Statistics, 1983). At the time of this recommendation, it was not known that the dietary fibre intake of children was inadequate to achieve optimal health (IOM, 2001), which suggests that these targets may be set too low.

Dietary fibre guidelines for intake in children have typically erred on the side of caution. There was insufficient data in children for the National Academy of Sciences committee to determine an EAR (Estimated Average Requirement) and thus an RDA (Recommended Dietary Allowance) for dietary fibre. Due to this, an Adequate Intake (AI) for dietary fibre was set using data extrapolated from adults. It is anticipated that the AI will meet or even surpass the requirements of most people in each life stage and gender group, however, it should be used with caution in making assessments of any type (Otten *et al*, 2006). Also, when usual intakes are compared to the AI of a nutrient, one can only conclude whether or not the intake is above the AI (Otten *et al*, 2006).

For dietary fibre, the AI is based on energy intake and is calculated as 14 g/1,000 kcal consumed. This level of dietary fibre consumption has been found to be protective against coronary heart disease in adults (Otten *et al*, 2006). Furthermore, the beneficial effects of fibre are believed to be related to the amount of food eaten (not to age or body weight) (IOM, 2002). On the other hand, energy requirements change

drastically throughout infancy, childhood and adolescence and most people would not know their usual energy intake (IOM, 2002). To make the recommendations more user-friendly, survey data from the Continuing Survey of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998 were used to calculate g/day of total fibre by multiplying the median energy intake for each age and gender group (Table 2.3). Individuals with higher or lower intakes would adjust the recommendation accordingly.

Table 2.3 Adequate Intake for Total Fibre
Based on 14 g/1000 kcal x Median Energy Intake

Group	Age (years)	Total Fibre (g/day)
Children:	1-3	19
	4-8	25
Boys:	9-13	31
	14-18	38
Girls:	9-13	26
	14-18	26

The recommended intake based on the AI is substantially higher than the amounts recommended by the "age plus five" guideline. The following examples are intended to illustrate the differences between the AI and "age + five" guideline. A one year old should get 19 g of fibre per day based on the AI value, compared to 6 g/day based on the "age + five" guideline. Other examples of comparisons illustrate the differences between the two recommendations. For example, based on the AI, a 10 year old girl should get 26 g of fibre per day compared to 15 g (age + five guideline). An 18

year old male should get 38 g of fibre (AI) compared to 23 g (age + five guideline). The difference between the two can range from 11-15 g per day.

It should be kept in mind that the AI takes into account the consumption of functional fibre sources, whereas previous guidelines did not. Some studies have used a hypothetical estimated intake of functional fibre of 5 g per day in children (Kranz *et al*, 2005). In that case, the above-mentioned differences in recommended fibre intake for the two methods would be in the range of 6-10 g.

The values for some sources of dietary fibre, particularly functional fibres, are not found in current nutrient databases (Kranz *et al*, 2005) (see section 2.2.4). It is therefore necessary to estimate functional fibre due to a lack of data, which may lead to over or underestimation.

It was thought, at the time of publication of the AI for fibre, that human milk did not contain dietary fibre, and therefore was not required for health in infants (Otten *et al*, 2006). It has since been found that there is approximately 12 g of nondigestible oligosaccharides per litre of breast milk (Edwards & Parrett, 2003). Others have reported variable levels of oligosaccharides, such as 10-12 g/L (Veereman-Wauters, 2005), 15 g/L (Brand-Miller & McVeagh, 1999), and 5-10 g unbound oligosaccharides per litre (Bode, 2006). Some of the differences in values are explained by daily variations in composition, duration of lactation and the mother's genetics (Coppa *et al* 1993). As breast milk is the optimal choice for nutrition for infants, a guideline for setting an AI for 0-6 month old infants could be based on the amount of non-digestible oligosaccharides in breast milk.

For example, a seven-kilogram infant would require approximately 700 kcal/day to meet energy requirements for growth, as well as deposition of body tissue. To meet this requirement, an intake of approximately 1000 mL of breast milk would likely be sufficient (68 kcal/100 mL, therefore, 680 kcal/d). The infant would, therefore, consume 5-15 g of oligosaccharides daily, which translates into 7.5-22 g/1000 kcal consumed. Perhaps the average of this range could be selected as the AI recommendation, which is approximately 15 g/1000 kcal of energy intake for infants 0-6 months. Interestingly, this is similar to the current AI for other life stage/age groups. Additional research would be beneficial in confirming the amount of variation in the oligosaccharide content of breast milk.

For a one year old child who weighs about 10 kg, the energy requirement is about 1000 kcal/day. Breast milk intake will be reduced to about 500 mL/day (2.5-7.5 g/day of oligosaccharides or an average of 5 g/day) or even less if whole cow's milk is introduced, as is often the case in developed countries at this age. Introduction of cow's milk, although common practice, may not be ideal due to the loss/decrease of oligosaccharides.

It might be difficult to achieve an additional 10 g of dietary fibre (to get 15 g/1000 kcal) for this child. However, a study of the usual intakes of dietary fibre for American toddlers in 2002 (1-2 year olds, n=998) showed a mean intake of 8 g/day (Devaney, Ziegler, Pac, Karwe, & Barr, 2004). It seems that the AI may be achievable for children two years of age and beyond, particularly if breast milk is continued throughout the first two years of life, as recommended by the World Health Organization.

2.2.7 Fibre Intakes of Children

There are a number of studies providing information on the dietary fibre intake of children in North America, based primarily on nationwide intake data. Kranz *et al* (2005) examined data from the Continuing Survey of Food Intake by Individuals 1994-1996, 1998 in the U.S. to determine the implications of the new Dietary Reference Intakes for fibre. It was found that children between 2-5 years of age consumed less than the recommended 14 g/1000 kcal of energy intake. In comparison, using the "age + five" rule for fibre intake, many still did not meet the minimum recommendation.

Earlier research also supports the inadequate fibre intake of many children. Using USDA data, Saldanha (1995) found that the majority of children in the various age-sex groups were not meeting the fibre intake recommendations as per the American Health Foundation. Further to this, they found that the intake of fibre dropped slightly from 1977-1978 to 1987-1988.

Another study by Nicklas *et al* in 1995 examined data obtained in the Bogalusa Heart Study. This was a large-scale epidemiological study spanning some 20 years, which followed a pediatric population into adulthood. The cross-sectional sample consisted of five cohorts of 10 year old children (1976, 1978, 1981, 1984, 1987). Sixty-five percent of this group consumed a range of 5 to 15 g of dietary fibre per day (Nicklas *et al*, 1995).

A statistically significant higher dietary fibre intake was found in 1981 (6.0 g/1000 kcal) compared to 1978 (5.3 g/1000 kcal). This is in contrast with the findings of Saldhana (1995) who observed a decrease in dietary fibre intake for three of the age groups (2-5 and 6-11 year old children and 12-18 year old males) from 1977-78 to

1987-88. The mean total daily dietary fibre intake stayed at approximately the same level throughout the study period.

The Bogalusa Heart study also identified and followed two cohorts of 13 year old children (1976, 1987). Once energy intake was adjusted, there was no significant difference in the dietary fibre intake of 13 year old children in 1976 versus 1987. Females aged 12-18 years maintained the same dietary fibre intake during this period.

There is some recent data on the intakes of Canadian children through the 2004 Canadian Community Health Survey Cycle 2.2. It was found that 1-3 year old children (n=2117) consumed a mean of 10.2 g/day of dietary fibre, while 4-8 year old children (n=3235) consumed a mean of 13.5 g/day (Health Canada, 2006). The AI for the age groups mentioned is 19 and 25 g/d, respectively, which does not include functional fibre sources. This indicates a gap between the intake of Canadian children and the AI for dietary fibre, similar to that seen with American children.

The literature provides some information on the food sources of fibre in the diet of children. Kranz *et al* (2005) found that low-fibre fruits (e.g. canned/processed fruit such as fruit cocktail and applesauce) provided the most dietary fibre, followed by soy and legumes, high-fibre ready-to-eat cereals, high-fat grain-based mixed dishes (e.g. pizza), and high-fat salty snacks. Fresh fruit and vegetables were consumed in small amounts and contributed very little to fibre intakes.

An interesting finding by Kranz *et al* (2005) was that children who ate the most fibre also had the most nutrient-dense diets. For example, children aged 2-3 years old in the highest quartile of fibre consumption ate nearly double the servings of fruit and

grain products, when comparing them to those in the lowest quartile, supporting a possible relationship between foods high in fibre and nutrient density.

In contrast to North American children, dietary fibre intake was reported in 410 Nigerian children and revealed a mean intake of 12 g for 2 year old children and 19.4 g for 5 year old children. These levels of dietary fibre intake are much higher than those reported for North American children. Interestingly, they still fall short of the DRI recommendations (e.g. 19 g dietary fibre/day for 1-3 year olds and 25 g/day for 4-8 year olds). Energy intakes were not reported in this study so energy-adjusted comparisons to the AI (i.e. 14 g/1000 kcal) cannot be made.

2.2.8 Potential Side Effects of High Dietary Fibre Intake in Children

Historically, guidelines for dietary fibre intake in children have erred on the side of caution. It was thought that high amounts of dietary fibre would result in nutrient imbalances (McClung *et al*, 1995). Many fibre-containing plant foods contain phytates, which have the ability to bind to minerals such as iron and calcium, thereby inhibiting their absorption. There is minimal data to support dietary fibre having detrimental effects on nutrient balances or growth (McClung *et al,* 1993; McClung *et al*, 1995; Williams, Bollella, & Wynder, 1995).

One study has been performed in constipated children, which evaluated the safety of supplemental fibre. The subjects were allowed to choose from five different fibre supplements available commercially at the time of the study. The children, who were 4-12 years of age, were supplemented at a level of 0.25 g/kg body weight, which was half of the level recommended by the American Academy of Pediatrics 1993

guideline. There were no significant changes in blood mineral levels of calcium, phosphate, copper and iron (McClung *et al*, 1993). Ferritin levels decreased in some subjects but no cause could be determined by the authors of this study. There has also been concern that energy intake would be reduced with a high intake of dietary fibre (Williams, 2006), although in the context of today's childhood obesity epidemic, this may not be as concerning as it has been in the past. This study did not report any changes in energy intake.

In fact, several animal studies have shown enhanced absorption of certain minerals such as calcium and magnesium (Coxam, 2005; Weaver, 2005). Additional clinical trials in humans are required to confirm the specific types of dietary fibre sources. Currently, fructans such as inulin and oligofructose are under investigation.

It can be argued that receiving dietary fibre through food is preferred to fibre supplements. There is concern that excessive dietary fibre may be in some way harmful. However, it is interesting to note that no tolerable upper intake level (UL) was set for dietary fibre, which may indicate that there is no excessive intake. For example, if one considers the consumption of a glass of apple juice (no dietary fibre) compared to an apple, the sheer bulk of high-fibre foods is self-limiting (Kranz *et al*, 2005). Some experts argue, however, that the use of fibre supplements and the addition of fibre to foods may necessitate setting an UL in the future (Englyst, Liu, & Englyst, 2007).

Research has demonstrated that two different fibre supplements were well-tolerated in constipated children. One was a soluble fibre source (Loening-Baucke *et al*, 2004) and the other an insoluble fibre source (Castillejo *et al*, 2006) (see section 2.6.3). No adverse events were reported in either study.

2.3 ISOLATED DIETARY FIBRE SOURCES

2.3.1 Introduction

There are a number of fibre sources that have been isolated for use in foods or as supplements. In Canada, the novel sources that are approved include apple pomace, oat hull fibre, pea hull fibre, psyllium seed husk and sugar beet fibre (see Table 2.2). Other isolated sources, such as inulin, are considered to be more traditional dietary fibre sources.

2.3.2 Pea Fibre

Field pea is classified as a grain legume (pulse) with many properties similar to those of lentils (Grant, Duncan, Alonso, & Marzo, 2003). For example, the fibres from pea have the ability to bind bile acids (*in vitro)* (Grant *et al*, 2003). Also, there is some research suggesting that fermentation occurs in the colon with a resulting production of butyrate (*in vivo*) (Grant *et al*, 2003). Resulting actions of these characteristics in the host include laxation, as well as lowered cholesterol and blood glucose levels. However, the research is conflicting depending on the anatomical source of the fibre (e.g. testa or cotyledon), the preparation method (raw, cooked or extruded) and the type of peas used (yellow or green field peas).

The finely ground testa, or hull as it is commonly referred to, of yellow field pea consists primarily of dietary fibre (e.g. Best Pea Fibre; Best Cooking Pulses, Portage La Prairie, MB, Canada; total dietary fibre 89%, insoluble 82%, soluble 7%). Best Pea Fibre is approved by the CFIA for addition to bakery goods and cereals only, and it is also permitted to label the dietary fibre content coming from ground pea hull fibre in

foods. In terms of its applications in the food industry, it is suitable as a replacement for wheat, soy, oat or sugar beet fibre. More specifically, it is touted as a good addition to foods such as noodles, cookies, muffins, graham crackers and other baked goods.

One study using finely ground testa from yellow field peas has been performed in a group of institutionalized elderly (n=114). The pea hull fibre was added to 3-4 foods per day and resulted in an increase in fibre intake of 1.9-6.4 g/day (mean = 3.1 g/day). The results of this study indicated a significant increase in stool frequency with fibre supplementation in this population (Dahl, Whiting, Healey, Zello, & Hildebrandt, 2003).

A study performed by Guedon *et al* (1996) used 15 g/day of ground pea hull, which was sprinkled on food for three weeks. The findings of this study included the acceptability and digestive tolerance of pea hull fibre, although no change in stool frequency was observed (Guedon *et al*, 1996). The study was performed in six healthy young men with normal bowel habits.

Dubois *et al* (1995) studied the effects of pea hull fibre (Sofalite F 179; Dasa, Torcy, France) and soybean fibre (hull) on cholesterol and lipid levels in six normolipidemic males. Each form of fibre was studied individually with an interval (7-15 days) between test meals. The subjects consumed 10 g of pea hull fibre, which was composed of 0.94 g soluble fibre and 9.06 g of insoluble fibre. A nearly two-fold reduction in postprandial serum-esterified cholesterol over the time period of 0-7 hours was found following the pea fibre test meal.

The authors surmised that this effect was due to the change in composition of the chylomicrons in the presence of the pea hull fibre, with a corresponding decrease in

the absorption of cholesterol as well as improved excretion of cholesterol in the small intestine (Dubois *et al*, 1993). This is an interesting finding in light of the lack of development of viscosity with pea hull fibre. Viscosity is thought to be the main modulator in lowering serum cholesterol levels (Dikeman & Fahey, 2006). The results also demonstrated a decrease in the overall postprandial serum cholesterol response, which remained significant at seven hours. Insulin response and postprandial triglyceridemia were not affected by the addition of either type of fibre (pea or soybean) to the control test meal. Additionally, these researchers found that chylomicron cholesterol levels were reduced significantly (by 31%) following the pea fibre meal. Pea fibre reduced postprandial HDL cholesterol levels and cholesterolemia for seven hours. It is proposed that this cholesterol-lowering effect lasts beyond the initial fibre supplementation (Dubois *et al,* 1995). Limitations of these studies included small sample size, male subjects only and short study length.

A Danish study also looked at the addition of pea fibre to the diet and examined the effects on fasting blood lipid concentrations and on postprandial lipemia in two separate studies. The pea fibre was baked into bread and consumed by subjects in that form in both studies. The pea fibre contained 61.7 g of total dietary fibre per 100 g, which was 31.7 g of insoluble and 30.0 g of soluble fibre, consisting of intact pea cell walls with the majority of the starch removed (Sandstrom, Hansen, & Sorensen, 1994).

The first of these, study A, used 33 g of pea fibre (corresponded to 20 g dietary fibre) for a total daily dietary fibre intake of 36 g (20.7 g soluble and 15.3 g insoluble fibre) in five men and six women (crossover design). This was compared with a low fibre diet (17 g/day). They found that there was a tendency towards lower total

cholesterol concentrations in subjects after consuming the pea fibre diet. As a result, the ratio of total cholesterol to HDL cholesterol was significantly lower after the pea fibre diet (Sandstrom *et al*, 1994). Total and VLDL concentrations were also affected and were significantly lowered following the pea fibre diet (Sandstrom *et al*, 1994).

The second study, study B, examined eight healthy male volunteers who consumed the pea-fibre-fortified bread at breakfast (12 g of pea fibre preparation, which provided 7.4 g dietary fibre) and lunch (15 g, which provided 9.3 g of dietary fibre). No significant differences were found in terms of plasma glucose levels, although plasma insulin levels were significantly reduced in the subjects following the consumption of the pea fibre diet compared to the control diet (Sandstrom *et al*, 1994). They also found that plasma triglyceride levels were reduced after the lunch meal with the pea fibre diet compared to the control (Sandstrom *et al*, 1994). Overall, significant effects were found with respect to insulin concentrations and triglyceride metabolism.

2.3.2 Inulin

Inulin is a prebiotic fibre that has been studied extensively in the last several years. However, because this is an emerging area, discrepancies in terms of classification are rampant in the literature (Douglas & Sanders, 2008), even as the definitions for prebiotics are undergoing constant changes as new research is happening (Gibson, Prober, Van Loo, Rastall, & Roberfroid, 2004; Roberfroid, 2007). Douglas (2003) proposed three major groups of fructan prebiotics: short chain fructooligosaccharides (scFOS), oligofructose and inulin. Other authors suggest a broader term for these substances namely “resistant short-chain carbohydrates”, which

include the fructans (inulin and fructooligosaccharides), alpha-galactosides and other similarly manufactured compounds (Englyst *et al,* 2007). Inulin and oligofructose are the only currently recognized nondigestible oligossaccharides meeting all of the criteria required for "prebiotic" status (Roberfroid, 2007).

The criteria required for a substance to achieve prebiotic classification include: 1) the resistance to digestion of the substance by gastric acidity, enzymes and absorption along the intestinal tract, 2) the fermentability (by intestinal bacteria) of the substance, and 3) the selectivity of the stimulation of intestinal bacteria with a benefit on the host's health (Gibson *et al*, 2004; Roberfroid, 2007). A prebiotic, when ingested by humans, is a substance that promotes the growth of beneficial bacteria, such as bifidogenic and lactobacillic bacteria, in the intestines.

Inulin is a naturally occurring oligosaccharide composed of fructose (Taylor & Mahenthiralingam, 2006). It is classified as a carbohydrate, specifically as a "fructan", and it is derived from the roots of chicory and Jerusalem artichoke, and is also found naturally in foods such as onions, leeks, bananas and wheat. Inulin derived from chicory root is approved for use as an ingredient by the Canadian Food Inspection Agency (section 2.2.5).

As part of the group of β(2→1) fructans, inulin has varying chain lengths and is resistant to digestion by human small intestinal enzymes due to its beta configuration (Roberfroid, 2002; Van Loo *et al*, 1995). The IOM has classified inulin as a functional fibre, as it has been isolated and has been shown to have beneficial physiological effects in humans (Douglas & Sanders, 2008). Oligofructose is a fructan that is enzymatically hydrolyzed from inulin (Roberfroid, 2002). The chain length of such prebiotics is

referred to as the degree of polymerization (DP) and for chicory inulin it is up to 25 (Roberfroid, 2002), with the same author suggesting a DP of up to 60 in more recent years (Roberfroid, 2007). Oligofructose, when derived from chicory inulin, has a DP of only 3-5 (Van Loo *et al,* 1999), while other researchers suggest a DP of 2-8 (Roberfroid, 2007).

The benefits of inulin are derived from its fermentation in the colon and are both local and systemic (Tungland & Meyer, 2002). It is fermented selectively by Bifidobacteria and Lactobacilli (Kruse *et al*, 1999; Causey, Feirtag, Gallaher, Tungland, & Slavin, 2000), which are of particular interest in human health (Douglas & Sanders, 2008). They act by modifying intestinal health to a more healthful balance (Roberfroid *et al*, 1995) through a positive effect on colonic function and metabolism (Douglas & Sanders, 2008), as well as by minimizing proliferation of potentially harmful bacteria (Burkitt *et al*, 1974; Kruse *et al*, 1999). There is some research showing that there may also be stimulation of a *Clostridium coccoides-Eubacterium* cluster with the ability to produce butyrate (Kleessen *et al*, 2001). However, more research is required to elucidate which inulin derivatives have these effects (Roberfroid, 2005).

Inulin and oligofructose can increase stool frequency and stool mass due to their fermentation and resulting increase in bacterial mass (Roberfroid, 2002). Studies have shown that 1.5-2 g of stool weight can be achieved per gram of non-digestible oligosaccharides consumed (Gibson & Roberfroid , 1995; Den Hond, Geypens, & Ghoos, 2000).

In a consensus statement report, Van Loo *et al* (1999) acknowledged that the role of oligosaccharides could be significant from a public health point of view. In

particular, the elderly and young children tend to experience constipation more frequently and may benefit from the ingestion of oligosaccharides. Inulin and oligofructose intake in the U.S. was estimated at 1-4 g/day compared to 3-11 g/day for Europeans (Van Loo *et al*, 1995). Intakes today would be expected to be higher given the increased use of inulin and FOS in the food industry; however, there is no data at present to confirm this. Research has shown that the prebiotic effect can be achieved with ingestion of 5-15 g/day over a few weeks (Roberfroid, 2002).

In terms of the side effects of inulin ingestion, Kruse, Kleessen, & Blaut (1999) found that some symptoms of flatulence and bloating were reported in individuals consuming 22-34 g/day (dependent on energy intake). The researchers reported that the side effects resolved within 2-4 weeks of ingestion of this level of inulin (Kruse *et al,* 1999). This level is much higher than that typically consumed by Westerners and is also higher than necessary to achieve a prebiotic effect (see above). Also, study subjects reported that this level of gastrointestinal discomfort was acceptable (Kruse *et al,* 1999).

Another study in adults used inulin (DP ~25) in subjects with low stool frequency compared to a placebo diet. Fifteen grams of inulin was consumed over a period of two weeks and the side effects examined were abdominal cramps and flatulence. The authors found an increased incidence of each in the treatment group; however, this did not reach significance (flatulence: $p=0.24$; abdominal cramps: $p=0.12$) (Den Hond *et al*, 2000).

2.4 NORMAL BOWEL HABITS IN CHILDHOOD

2.4.1 Bowel Frequency and Stool Characteristics

A number of studies have been performed to determine the normal bowel habits of children. This can vary depending on a number of factors such as culture, usual diet, age and stage of development. Yong and Beattie (1998) determined by way of questionnaire that 84% of English children aged 4-11 years passed at least one stool per day. Based on symptoms identified by parents, 34% of these children had experienced constipation at some point and 5% had constipation for more than six months. Almost all children had a bowel movement frequency between three times per day and once every other day. Another British study, this time in a cohort of children aged 1-4 years (n=350), found that 96% had stool patterns between three bowel movements daily to one bowel movement every other day (Weaver & Steiner, 1984).

Another group studied Italian children aged 3-10 years and found a bowel movement frequency of 6.9 ± 2.6 stools per week (Paese, Staiano, Bausano, Cucchiara, & Corazziari, 1985). Based on these findings, the authors determined abnormal bowel frequency in this age group to be less than three times per week (or more than 14 per week). The sample size was relatively small (n=71) and may not be applicable to populations in other countries or cultures. However, similar results were found in another Italian study that looked at bowel frequency in children (Fontana *et al*, 1989), which serves to strengthen the earlier findings. In this study, subjects were divided into three age groups with larger sample sizes than performed by Paese *et al* (1985): 1-3 years (n=105), 3-6 years (n=121) and 6 years and older (n=139). Their findings were consistent with Paese *et al* (1985), with 1-3 year olds having 1.4 stools per day, 3-6 year

olds having 1.1 stools daily and children 6 years and up having 1.0 stool per day (Fontana *et al*, 1989). The authors noted a wide range of inter- and intravariability in stool frequency.

A more recent Italian study reported bowel frequency in 3-12 year olds as being 6.3 ± 2.5 evacuations per week (Corazziari, Staiano, Miele, Greco, & Italian Society of Pediatric Gastroenterology, Hepatology, & Nutrition, 2005). The study group was large for this age range (n = 2086) and they found no difference in stool frequency between the sexes for any age group. These researchers also examined the relationship between stool frequency and stool consistency. For all children, the mean bowel frequency had a statistically significant inverse relationship with increased stool consistency ($p < 0.001$) (Corazziari *et al*, 2005). For example, children whose stool was identified as being soft passed more bowel movements than those with hard or pellet-like stools.

A study of the bowel habits of American children aged 3-10 years of age was performed (Bloom, Seeley, Ritchey, & McGuire, 1993). Each age group was analyzed individually and the frequency of bowel movements was determined (see Table 2.4). As other studies have shown, frequency of bowel movements declines with age, as they found a statistically significant negative relationship between age and bowel frequency (per week). These findings are consistent with those reported by Paese *et al* (1985).

Table 2.4 Bowel Movements by Age Group*

Age Group (years)	Number of Patients	Number of Bowel Movements per Week (mean ± SD)
3	137	7.6 ± 2.7
4	149	7.1 ± 2.5
5	118	6.9 ± 2.4
6	100	6.5 ± 1.7
7	101	6.7 ± 2.0
8	79	6.6 ± 2.4
9	78	6.3 ± 1.9
10	76	6.7 ± 2.2

*Adapted from Bloom *et al*, 1993.

Some studies have shown that there are no statistically significant differences in stool frequency between male subjects and female subjects for healthy preschool and school-aged children (Corazziari *et al*, 2005; Bloom *et al*, 1993). Others have studied children by age group only and have analyzed male and female subject data together (Fontana *et al*, 1989; Weaver & Steiner, 1984).

Burmese children, aged 1-4 years, were studied by Myo-Khin, Thein-Win-Nyunt, Kyaw-Hla, Thein-Thein-Myint, & Bolin (1994). The mean stool frequency in a cohort of children was 6.98 ± 1.94 per week. Of particular note in this study is that no statistically significant findings (in terms of stool consistency, weight and volume) were found between boys and girls and between age groups. A difference between diet (adult-type versus partially-weaned) and the observed stool characteristics was not found based on 7-day food records (Myo-Khin *et al*, 1994). However, dietary fibre intakes were not reported in this study.

Thai children have also been found to have bowel frequency rates similar to those of their Western counterparts. Osatakul, Yossuk and Mo-suwan (1995) found that stool frequency for 2-3 year olds was 1.04 per day. However, mean stool volume (35.4

± 7.6 mL) produced by Thai children was higher than that reported by Western researchers (Osatakul *et al*, 1995). Weaver and Steiner (1984) found that British infants produced stool volumes of approximately 5-10 mL on average, while the majority of older children produced 25 mL of stool. This suggests that stool frequency, consistency and volume are important when considering bowel habits. The authors of the Thai study speculated that some of the differences in bowel habits of the Thai children could be due to higher dietary fibre intake (Osatakul *et al*, 1995).

Walker and Walker (1985) also found differences in these bowel parameters, which they equated to differences in diet, particularly dietary fibre content (the relationship between stool characteristics and dietary fibre is discussed in section 2.6). They studied rural black children, urban black children and white children in South Africa who were 1-4 years old. They compared and contrasted these groups to determine geographic and/or ethnic differences. These researchers found that black children (whether rural or urban) had a statistically significant higher stool frequency than white children. The rural black children had 1.9 bowel movements per day and the urban black children had 1.8 bowel movements per day, whereas the white children had 1.5 bowel movements daily (Walker & Walker, 1985).

One other study examined defecation patterns and intestinal transit in Nigerian children (Akinbami, Erinoso, & Akinwolere, 1995). Four hundred and ten children between the ages of 6 months and 5 years of age were studied. The assessment tools employed included a questionnaire and carmine red marker, which was used to assess transit time. These authors found that the majority (95%) of subjects had a bowel movement 1-3 times per day with a steady decrease in the mean stool frequency with

advancing age ($r = -0.8$, $p<0.01$) (Akinbami *et al*, 1995). The range was found to be from once every other day to five times per day. Mean bowel movement frequency was reported in chart form in this study and is approximated as follows: for 6-11 month old infants, the mean frequency was 2.5 bowel movements (BMs) per day, for 12-23 month old toddlers the mean frequency was 2.1 BMs, for 24-35 month old toddlers it was 1.7 BMs, and 1.4 BMs were reported for 35-60 month old children (Akinbami *et al*, 1995).

Overall, the findings of these two studies (Akinbami *et al*, 1995; Walker, & Walker 1985) indicate higher stool frequency for African children compared to Italian children in similar age groups (Fontana *et al*, 1989; Corazziari *et al*, 2005; Paese *et al*, 1985), Burmese children (Myo-Khin *et al*, 1994), British children (Weaver & Steiner, 1984) and American children (Bloom *et al*, 1993).

In a sub-group of 98 children in the study of Nigerian children, the mean transit time (mouth to anus) was found to be 18.3 hours with a range from 5.25 to 30 hours (Akinbami, 1995). A significant difference in transit time was found for children over three years of age (mean: 15.4 hours) compared to children less than three years of age (mean: 23.8 hours; $p < 0.05$). In terms of stool volume, it was found that 78% of the children (n=410) passed approximately 50-75 mL of soft stool, which is a great deal more than Thai (mean = 35.4 ± 7.6 mL) (Osatakul *et al*, 1995) and especially Western children (range = 5-25 mL) (Weaver & Steiner, 1984). This may be related to the higher dietary fibre intake (12-19.4 g/day) of the Nigerian children.

The data from many of these studies is dated and it is possible that diet and stool characteristics have changed in the interim. However, this does provide a summary of the available data on bowel patterns in healthy children.

2.4.2 Intestinal Transit Time in Children and Adults

Colonic transit time in children has not been studied extensively (Wagener, Shankar, Turnock, Lamont, & Baillie, 2004), although there are a few studies available using ingested radiopaque markers, particularly in constipated children (de Lorijn *et al*, 2004; Gutierrez, Marco, Nogales, & Tebar, 2002).

Wagener *et al* (2004) examined colonic transit time (CTT) in 22 healthy children (median age = 10 years, ranging from 4-15 years) and found a mean total CTT of 39.6 hours (SD = 21.4 hours, range = 7.2 - 86.4 hours). Results from six other studies were then used to compare their results. The researchers used various methods, populations and age groups to examine transit time, and the means for CTT range from 22.4 to 37.8 hours (Wagener *et al*, 2004). One study in children and adults found that the mean transit time of adults was slightly longer compared to children but this did not reach significance (39 ± 5 hours vs. 29 ± 4 hours, t = 1.73; p = NS) (Arhan *et al*, 1981).

Many factors in adults are known to affect transit time such as diet (Davies, Crowder, Reid, & Dickerson, 1986) and stress (Bouchoucha *et al*, 1992) but it is unclear if these effects are the same in children. Children with constipation do appear to have longer CTT than their non-constipated counterparts. For example, Gutierrez *et al* (2002) found a CTT of 29.08 ± 8.30 hours for 30 healthy controls compared to 49.57 ± 25.38 hours for 38 constipated children ($p<0.001$).

It is difficult to compare data from the available trials due to the heterogeneity of the groups and the different methodologies employed. Also, large differences in inter-individual variation were found even among healthy subjects with “normal” transit time. Due to this, research where subjects are compared to themselves may be more

valuable to establish baseline patterns in healthy subjects. One study examined the baseline (normal) transit time of 66 healthy adults and then induced constipation (slow transit) using loperamide and in turn induced diarrhea (rapid transit) with senna (Lewis & Heaton, 1997). It was found that the appearance of the stool (stool form) at baseline correlated highly with the whole gut transit time (WGTT) ($r = - 0.54$, $p = 0.001$) (Lewis & Heaton, 1997) and a tool, the Bristol Stool Form Scale, was developed. The authors concluded that this tool provides a valid means of assessing whole gut transit time.

2.5 CONSTIPATION

2.5.1 Definition and Proposed Diagnostic Criteria

Many research articles have been published on constipation. However, most are review papers and there is a relative paucity of original articles. This lends itself to a debate on the definition, evaluation, treatment and etiology of constipation.

Constipation has been defined in a number of ways in the literature. In a survey of 2680 Italian children, the criteria used for analysis of pediatric constipation were the Loening-Baucke (1993) criteria, which include at least two of the following:

- Two or more encopresis episodes per week,
- Periodic passage of very large amounts of stool once every 7-30 days,
- A palpable abdominal or rectal mass on physical examination.

Many groups have since devised their own criteria for diagnosis of constipation in children.

The North American Society for Pediatric Gastroenterology and Nutrition (NASPHGAN) committee proposed that constipation is defined as a “delay or difficulty

in defecation, present for 2 or more weeks and sufficient to cause significant distress to the patient" (Baker *et al*, 1999). This group also evaluated the research literature in order to develop clinical practice guidelines (see section 2.5.3).

There were no randomized controlled studies on the effects of dietary fibre supplements on stools at the time of publication by the NASPHGAN group. This group does, however, provide a level III guideline that "a balanced diet, containing whole grains, fruit and vegetables, is recommended as part of the treatment of constipation" (Baker *et al,* 1999). This level of evidence is not very compelling as it is based on the opinions of respected authorities with clinical experience, descriptive studies, and reports of expert committees.

The most widely used diagnostic criteria for defecation disorders in recent years are known as the Rome II criteria. The American College of Gastroenterology Chronic Constipation Task Force (Brandt *et al*, 2005) argued that this tool is too unwieldy for use in clinical situations and that it better suits identification of a uniform study sample.

The Rome II criteria have since been replaced by the Rome III version (Hyman *et al,* 2006), and changes were made which may address some of the concerns brought forward by the Task Force. For example, they reduced the timeframe of history of symptoms of functional constipation in infants and toddlers from 12 weeks to one month (Hyman *et al*, 2006). The duration of symptoms was also reduced for children and adolescents from three months to two months (Rasquin *et al,* 2006).

The rationale behind this reduction in both cases was that it has been recognized that the earlier the diagnosis, the better the chance of success of the treatment (Evidence Level C) (Loening-Baucke, 1993; Van Ginkel *et al,* 2003). The authors further stressed

that diagnosis need only be made on the basis of history and physical assessment and does not require additional testing (Hyman *et al,* 2006).

Table 2.5 Childhood Functional Defecation Disorders: ROME III Diagnostic Criteria*

Disorder	Features
Infant dyschezia	• Age less than six months and must include both of the following: • At least ten minutes of straining and crying before passage of soft stools • Infant is otherwise healthy
Functional constipation (Infants and toddlers)	• Must include one month of *at least two* of the following in infants up to 4 years of age: 1. Stools passed ≤ 2/week 2. At least one episode per week of incontinence after the acquisition of toileting skills 3. History of excessive stool retention 4. History of painful or hard bowel movements 5. Presence of large fecal mass in the rectum 6. History of large-diameter stools that may obstruct the toilet
Functional constipation (Minimum of four years of age developmentally; insufficient criteria for a diagnosis of irritable bowel syndrome)	• Must include two or more of the following and criteria met must occur at least once a week for a minimum of 2 months prior to diagnosis 1. Two or fewer defecations per week 2. At least one episode per week of fecal incontinence 3. History of retentive posturing or *excessive* stool retention 4. History of painful or hard bowel movements 5. Presence of a large fecal mass in the rectum 6. History of large diameter stools that may obstruct the toilet

*****This chart has been adapted from Hyman *et al*, 2006 and Rasquin *et al,* 2006.

The ACGCC Task Force, in their recommendations for an evidence-based approach to the management of chronic constipation, suggests a broader definition that contains the more typical symptoms communicated by patients. Brandt *et al* (2005), in their report, have proposed the following criteria for diagnosing chronic constipation:

> Constipation is a symptom-based disorder defined as unsatisfactory defecation and is characterized by infrequent stools, difficult stool passage, or both. Difficult stool passage includes straining, a sense of difficulty passing stool, incomplete evacuation, hard/lumpy stools, prolonged time to stool, or need for manual maneuvers to pass stools (Grade C Recommendation) (p.S8).

Chronic constipation is further defined by this group as "the presence of these symptoms for at least three months" (Grade C Recommendation) (Brandt *et al*, 2005, p.S8). It should be noted that these recommendations considered the Rome II criteria, as the Rome III criteria were not yet published. In addition, this systematic review on constipation in adults did not specifically address pediatric constipation, which is known to have different characteristics compared to that of adults (Youssef & Di Lorenzo, 2001).

Other agencies have proposed their own definitions and criteria for a diagnosis of constipation. The American Academy of Family Physicians describes constipation as bowel movements less often than every two days, or as stools that are hard or painful to pass along with more regular bowel movements. They further determine "chronic constipation" as occurring for two weeks or longer. The Canadian Paediatric Society (2007) describes the symptoms of constipation as bowel movements that occur less often than usual, that are hard and dry, and/or painful or difficult to pass.

Bosaeus (2004) in his review of the effects of fibre on intestinal function (diarrhea, constipation and irritable bowel syndrome) states that constipation is a constellation of symptoms including "low bowel frequency (i.e. < three/week), straining, painful, hard and/or dry stool, incomplete rectal evacuation, irregular stool

expulsion, and abnormally small stools". However, this review was not specific to the pediatric population.

Yet another group has formed guidelines for the proposed terminology of constipation and related disorders (see Table 2.6). This group felt that the "current Rome criteria were too restrictive" (Benninga *et al*, 2005). The goal of this group was to reach a consensus on proposed terminology on childhood functional gastrointestinal disorders to facilitate the revision of the Rome II criteria.

There has been some criticism of the PACCT definition of chronic constipation, as it does not encompass those patients who experience hard stools that may be described as pebble-like, scybalous, or cylindrical cracked (Maffei & de Morais, 2005). This part of the definition was previously proposed by "the Boston Working Group" (Hyams *et al*, 2002). Maffei and de Morais (2005) argue that this definition was broad enough to cover both mild and more severe cases of constipation. The Boston working group (Hyams *et al,* 2002) proposed the following definition:

> Constipation is a symptom defined by the occurrence of any one of the following, independent of stool frequency: passage of hard, scybalous, pebble-like, or cylindrical cracked stools; straining or painful defecation; passage of large stools that may clog the toilet; or stool frequency less than three per week, unless the child is breast fed (p. S113).

Table 2.6 PACCT* Group's Recommended Terminology

Chronic Constipation	The occurrence of two or more of the following characteristics, during the last 8 weeks: - Frequency of bowel movements less than three per week - More than one episode of fecal incontinence per week - Large stools in the rectum or palpable on abdominal examination - Passing of stools so large that they may obstruct the toilet - Display of retentive posturing and withholding behaviours - Painful defecation
Fecal incontinence	Passage of stools in an inappropriate place
Organic fecal incontinence	Fecal incontinence resulting from organic disease (e.g., neurological damage or sphincter abnormalities)
Functional fecal incontinence	Non-organic disease which can be subdivided into: – Constipation-associated fecal incontinence – Non-retentive (non-constipation-associated) fecal incontinence
Constipation associated fecal incontinence	Functional fecal incontinence associated with the presence of constipation
Non-retentive fecal soiling	The passage of stools in an inappropriate place, occurring in children with a mental age of 4 years and older, with no evidence of constipation based on history and/or examination
Fecal impaction	Large fecal mass in either the rectum or the abdomen is present which is unlikely to be passed on demand. The fecal impaction can be demonstrable by abdominal or rectal examination or other methodology.
Pelvic floor dyssynergia	Inability to relax the pelvic floor when attempting to defecate

*PACCT: The Paris Consensus on Childhood Constipation Terminology (Benninga *et al*, 2005)

As mentioned, the many proposed definitions and diagnostic criteria make it challenging to compare the results of studies using different criteria. Future research would be greatly strengthened by a consensus among experts for evidence-based, pediatric-specific definitions for defecation disorders and constipation in particular.

2.5.2 Prevalence and Etiology

Constipation results in a significant number of visits to doctors, and patients are often referred to specialists, such as pediatric gastroenterologists (Loening-Baucke, 1993). Recently it was shown that 3% of all pediatric outpatient visits and 25% of gastroenterology referrals are related to constipation (Corraziari *et al*, 2005).

Constipation should be viewed as a symptom and not a disease (Keshtgar, Ward, & Clayden, 2004). The majority of cases of constipation in children cannot be attributed to an organic cause (Castiglia, 2001). Therefore, approximately 95% are termed functional or idiopathic constipation (Coughlin, 2003). However, organic causes such as Hirschsprung's disease, anatomic or neuromuscular irregularities, metabolic and endocrine disorders, and irritable bowel syndrome should be ruled out by an assessment performed by a physician, as these generally require treatment for the underlying cause of constipation (Youssef & Di Lorenzo, 2001).

Most researchers agree that the cause of functional constipation is multi-factorial (Borowitz *et al*, 2003). The most common cause cited by parents was an episode of a particularly large and/or painful bowel movement (Borowitz *et al*, 2003). The other main causes reported by parents were toilet training, starting daycare, travel and the transition from a liquid diet (breast milk or formula) to a solid diet (Borowitz *et al*, 2003).

Other researchers also cite irregular bowel habits such as defecation avoidance or stool withholding (Candy & Edwards, 2003; DiPalma & Gremse, 2001), as a potential cause of constipation. In some cases, this might occur in a child who is so absorbed in activities that he or she continuously ignores the urge to defecate. This

results in some practitioners and researchers terming constipation as behavioural (Ozokutan, Zoroglu, Ceylan, & Ozban, 2005). However, this group found that there were no significant behavioural problems in children with constipation when compared with a control group of children with inguinal hernia (Ozokutan *et al*, 2005).

If practiced over a long period of time, stool withholding can result in a condition termed "idiopathic megarectum" (Candy & Edwards, 2003). The rectum does not ordinarily serve as a storage place for stool but will begin to do so in these circumstances. The ability of the rectum to signal the time to defecate is lost and the result can be "overflow incontinence" (Candy & Edwards, 2003). This is sometimes misinterpreted as diarrhea by caregivers (DiPalma & Gremse, 2001).

Researchers are looking at other possible causes of constipation. For example, low dietary fibre intake has been associated with increased risk of constipation (Morais *et al*, 1999) (see section 2.6.3). There are a number of other causes that have been proposed, such as inadequate physical activity or fluid intake, but there is an overall lack of evidence to support or refute these causes (Young, Beerman, & Vanderhoof, 1998) (see section 2.5.3).

Medications can also have an effect on the frequency and consistency of bowel movements. Some medications known to cause constipation in children include antacids, analgesics (e.g., NSAIDs), anticonvulsants (e.g. phenytoin), diuretics, chemotherapy drugs, antihistamines, some antihypertensives and anticholinergics (e.g. atropine agents) (DiPalma & Gremse, 2001).

Slow transit constipation (STC) is emerging as a type of constipation previously considered "functional constipation". Slow colonic transit time can be identified using

new techniques. For example, multi-channel colonic manometry measures the number of high amplitude propagating contractions (HAPCs), which are thought to correspond with mass movements (Southwell *et al*, 2005). Another tool, scintigraphy, involves neuropeptide labelling of food followed by imaging (Southwell *et al*, 2005). Both of these measures help to identify cases where slow colonic transit time may contribute to constipation. The etiology of STC is currently theorized to be related to abnormal intestinal innervation (Southwell *et al*, 2005). Based on this working theory and the fact that constipation tends to run in families, a pilot study was conducted and five genes were identified that encode neurotransmitters which may be involved in STC (Garcia-Barcelo *et al*, 2007). Further research is required to elucidate these preliminary findings.

Research in the last decade has pointed to chronic constipation potentially being a manifestation of food allergies. In particular, recent research has examined milk hypersensitivity as a symptom or potentially a cause of constipation (Iacono *et al*, 1998), although further research on the role of milk hypersensitivity and constipation is required. Iacono *et al* (1998) studied 65 children with chronic constipation in a crossover design. These children had previously failed treatment with laxatives. They had a success rate of 68% (n=44) for children receiving soy milk and consuming a CMA-free diet (Iacono *et al*, 1998). This group attempted to aid in the adherence to the diet (i.e. CMP-free diet) by providing information and encouraging phone calls.

Another group investigated twenty-five chronically constipated children to assess response to a CMP-free diet (Daher *et al*, 2001). Seven patients (28%) responded to the CMP-free diet and two infants were found to have allergic colitis following rectal biopsy. The lower success rate may be due to the small group size (Daher *et al*, 2001).

Also, the diet was not as carefully monitored so it is possible that food containing milk was consumed inadvertently by subjects.

Twelve children with severe constipation who responded to a CMP-free diet were identified retrospectively. Nine patients were challenged with CMP after several months. Seven patients relapsed while two experienced no symptoms of constipation (Vanderhoof, Perry, Hanner, & Young, 2001).

Fifty-two consecutive pediatric patients who did not respond to treatment for constipation were enrolled. Twenty-four subjects improved on the cow's milk free diet, while an additional six improved on an oligoantigenic diet (a 45% success rate) (Carroccio *et al*, 2005). The food challenge was done in a double-blind, placebo-controlled manner. Improvement was measured by stool frequency, as well as repeat rectal biopsy (baseline and after 12 weeks on the elimination diet). The findings included a significant increase in the mucus gel layer in subjects who responded to the cow's milk free diet following the elimination diet compared to the baseline. All 30 subjects who were successful on the elimination diet had normal rectal endoscopy results (Carroccio *et al*, 2005). There was a selection bias, as the majority of patients seen at this centre have food-related intolerances.

Two very similar studies (conducted at the same centre) were performed by Scalici, Licastro, Manzoni, & Sferlazza (2005) and Iacono *et al* (2006). The first of these was done in 39 children with chronic constipation who were unresponsive to previous treatments and the second in 36 children. All of the subjects were placed on an elimination diet to exclude cow's milk and milk products. Diagnosis of cow's milk or multiple food intolerance was made on return of symptoms of constipation following

double-blind placebo-controlled food challenge. It was found that 17 patients in the first study and 14 subjects in the second study improved on the cow's milk free diet. A further three subjects improved on the more restrictive diet (oligoantigenic diet) in both studies, and a 48% success rate in both studies was reported (Scalici *et al*, 2005; Iacono *et al*, 2006).

Loening-Baucke (2005) performed a retrospective chart review. Of 185 infants less than two years of age, four were found to have cow's milk allergy (CMA) (Loening-Baucke, 2005). Of these, two (1%) had also experienced constipation. This study did not include any form of food elimination or challenge to determine the presence of CMA, which could explain the low prevalence of constipation thought to be related to CMA (Heine, 2006).

Although CMP allergy or intolerance may be implicated in chronic constipation in some children, the pathophysiology remains unknown. Animal studies have identified mast cells, eosinophils and T helper 2 cytokines, including Interleukin-13, as potential mediators of the allergy/intestinal dysmotility link (Murch, 2006). Some experts recommend that CMP intolerance should be considered in children who experience refractory constipation (Daher *et al*, 2001) but this remains controversial. Overall, supportive research demonstrates concomitant signs and symptoms of allergy/intolerance in some but not all study subjects, and additional research controlling for confounding factors such as dietary fibre intake is required.

2.5.3 Management and Treatment

Typical therapeutic recommendations for constipation include increased fluid and fibre intake, increased physical activity, family/behavioural therapy and medications (e.g. laxatives, stool softeners) (Amendola, De Angelis, Dall'oglio, Di Abriola, & Di Lorenzo, 2003). There is an overall lack of research to support increased fluid intake and, in fact, one clinical trial in the pediatric population refutes this traditional recommendation (Young *et al*, 1999). One study also shows a lack of significant difference in fluid intake for constipated children compared to non-constipated children ($p=0.579$) (Lee, Ip, Chan, Lui, & Young, 2008).

One group of researchers found that a combined therapeutic approach was effective in treating constipation. This included guidelines for increasing water and fibre intake, laxative use, and family therapy using a multidisciplinary approach including a pediatrician and a psychologist. Their findings showed an improvement in behavioural patterns within one month and a resulting regularity of bowel movements in 88% of children at the three-month follow-up (Amendola *et al*, 2003). The sample size of this study was 25 children (mean age: 4.7 years; range 2.1 to 7 years).

A 2001 Cochrane review found that the research was inadequate to recommend the use of stimulant laxatives in the treatment of constipation in children (Price & Elliott, 2001). The North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition more recently found that stimulant laxatives such as senna and bisacodyl should only be used in the short-term (Level of evidence: II-3, see Table 2.7 for explanation) (NASPGHAN, 2006).

NASPGHAN (2006) also suggests that barley malt extract, lactulose, corn syrup, or sorbitol may aid in softening stools in infants (III). In children, lactulose, sorbitol, mineral oil and magnesium hydroxide are safe and effective treatments for constipation (I). However, for infants, mineral oil and stimulant laxatives are not recommended (III) (NASPGHAN, 2006).

Table 2.7 Quality of Evidence Rating System

Categories of the quality of evidence	Description of the type of evidence
I	Evidence from a minimum of one well-designed randomized controlled trial
II-1	Evidence from a properly designed cohort or case-control trial (no randomization)
II-2	Evidence from well-designed cohort or case-control trials (more than 1 group/centre)
II-3	Evidence from prospective or retrospective studies with or without intervention
III	Based on expert opinion such as clinical experiences or reports from expert committees

Adapted from NASPGHAN, 2006.

Lactulose is marketed and sold as a laxative. It is synthetically derived from lactose through a heat treatment process (Pham & Shah, 2008), it is also thought to be bifidogenic (Salminen & Salminen, 1997), and it is known to be a nonabsorbable disaccharide (Chinda *et al*, 2004). It passes through the small intestine intact and is rapidly fermented by the resident microflora (Chinda *et al*, 2004). Based on its physiology, it could be considered a "dietary fibre-like" substance. It could possibly be considered in the future as a "functional fibre" based on the IOM classification (see section 2.2.2), as it could have similar beneficial physiological effects of other functional fibre sources such as inulin.

In terms of long-term treatment, there is limited evidence to support the use of polyethylene glycol electrolyte (PEG) solution in difficult-to-treat cases of constipated children (III) (NASPGHAN, 2006). A combined approach using medications and behavioural therapy is well-supported (I) (NASPGHAN, 2006). Biofeedback therapy is an option for intractable constipation (II-2) (NASPGHAN, 2006).

In infants, juices (e.g. pear, apple and prune juice) may decrease symptoms of constipation (II-3) (NASPGHAN, 2006). A balanced diet which includes whole grains, fruit and vegetables is recommended as part of the management of constipation in children (III) (NASPGHAN, 2006). This group did not analyze the data concerning dietary fibre intakes.

2.5.4 The Impact of Constipation

A large, prospective trial is required to establish a relationship between constipation and dietary fibre. However, some researchers suggest that such a study would have difficulty in obtaining funding due to the "benign" nature of constipation (Corkins, 2005). While there may be limited immediate effects on health, one could argue that the quality of life of children is adversely affected as a result of chronic constipation (Youssef *et al,* 2005). Also, it is quite prevalent in the population, which makes it a pervasive problem, at the least. Finally, it has been found that constipation, if unresolved in children, can continue into adolescence and beyond (van Ginkel *et al,* 2003), and it is assumed that the quality of life issues would continue.

There has also been a proposal in the literature that chronic constipation can cause oxidative stress in constipated children. Markers of oxidative stress, such as levels

of vitamins C and E and activity of catalase and superoxide dismutase, were examined in constipated children (n=70) and sex- and age-matched healthy children (n=70). It was found that the constipated children had significantly decreased levels of vitamins C and E, as well as superoxide dismutase and catalase activity (Zhou, Lou, Zhou, & Wang, 2005). The researchers surmised that this could indicate increased levels of oxidative stress in children with chronic constipation. The proposed mechanisms included increased exposure to the toxicants in stool for longer periods of time and resulting changes in the beneficial intestinal flora (Zhou *et al*, 2005). Another possibility is that the intakes of vitamins C and E are lower in constipated children, perhaps through an overall lower decreased energy intake secondary to a lack of appetite commonly found in this population.

There is an additional consideration when determining the importance of research on constipation and dietary fibre. Links have been found in epidemiological data that show an inverse relationship between body weight and high dietary fibre intake in adults (Slavin, 2005). There may also be benefits in addition to alleviating constipation, as dietary fibre is thought to play a role in the prevention of cardiovascular disease, hypertension, stroke, obesity, some cancers and type 2 diabetes (Martlett *et al*, 2002), which may relate to its impact on body weight.

For example, Pashankar and Loening-Baucke (2005) recently found an increased prevalence of functional constipation in obese children. These researchers surmised that a number of factors may be responsible for this finding such as activity levels, diet or even hormonal fluctuations. A recent study examined the relationships between dietary fibre, constipation and overweight in a group of urban adolescents (de

Carholvo *et al*, 2006). They found that a dietary fibre intake below the "age + 5 recommendation" was significantly associated with overweight in students attending private school (2.95, p=0.003 in females and 2.84, p=0.033 in males) (de Carholvo *et al*, 2006). No statistically significant association between constipation and low dietary fibre intake was found in this particular study group based on odds ratio analysis.

There may be a benefit for weight control with higher dietary fibre intakes in adults (Slavin, 2005), in addition to improved laxation and intestinal health. Dietary fibres cannot be digested in the human intestine, although most types are fermented by resident bacteria. This lack of digestion may be one of the mechanisms for lower obesity rates in populations that consume high amounts of dietary fibre (Kimm, 1995), as the decrease in energy absorption may be responsible for lower body weights.

2.6 CONSTIPATION AND DIETARY FIBRE

2.6.1 Effect of Dietary Fibre on Bowel Movements

Thai researchers looked at the relationship between bowel frequency and diet, particularly dietary fibre intake. They describe the Thai diet as a mixed diet with many different plant foods. Some of the foods given at an early age (6-12 months of age) include mashed bean, green leafy vegetables and pumpkin, foods that would not typically be introduced this early in a Western diet. The researchers suggested that this may explain the increased stool volume found in this population (Osatakul *et al*, 1995). However, in this study, the actual dietary fibre intakes were not reported.

There have been two randomized studies using fibre supplements to treat constipation in children (Loening-Baucke *et al*, 2004; Castillejo *et al*, 2006). They were

both successful in significantly increasing stool frequency and improving constipation in a majority of study participants (see section 2.6.3 for details).

Other researchers have attempted to elucidate the relationship between constipation and dietary fibre in children (Corkins, 2005; Guimaraes, Goulart, & Penna, 2001; Ip *et al*, 2005; McClung *et al*, 1995). All except one of these studies (Guimaraes *et al,* 2001) found a relationship between low dietary fibre intake and constipation in children. However, these studies merely show a relationship and do not prove causation.

A case-controlled study of Greek children (2-14 years old) found an incremental risk of constipation relative to lower dietary fibre intake (Roma *et al*, 1999). A similar study of Brazilian children (mean age 6.8 ± 3.2 years) found a lower intake of dietary fibre in the constipated group (13.8 g/d) compared to the control group (17.3 g/d) ($p=0.020$) (Morais *et al*, 1999). The children with the lowest intakes of dietary fibre (e.g. "age + 5 g" in this particular study) were more likely to experience constipation (odds ratio of 4.1; 95% confidence interval: 1.64-10.32) (Morais *et al*, 1999).

The same group in Hong Kong examined the intake of plant foods to determine any association with the prevalence of constipation. Three day food records for 368 children (3-5 years old), consisting of 28.8% constipated children based on Rome II criteria, revealed that the constipated group had a significantly lower intake of dietary fibre compared to the control group ($p=0.044$) (Lee *et al*, 2008). Further analysis revealed that this was likely related to a significantly lower intake of plant foods (vegetables, fruits and whole grain cereals) ($p=0.034$) (Lee *et al*, 2008). In addition to this, the constipated children had a corresponding lower intake of micronutrients

including vitamin C, folate and magnesium, which indicates an association between high fibre and nutrient dense foods.

2.6.2 Effect of Particle Size on Laxation and Fermentation in the Colon

There is some research investigating the effect of particle size of fibre on laxation. In one study, the effect of particle size on gastric emptying and small bowel transit in 12 subjects was investigated (Vincent *et al*, 1995). They confirmed that coarse bran significantly delayed emptying of the stomach, whereas fine bran did not. Increased small bowel transit time occurred but did not reach significance (Vincent *et al*, 1995).

Jenkins *et al* (1999) published two studies to address the effect of wheat bran particle size on both laxation and fermentation. The mean fecal output was similar for both fine and coarse wheat bran and significantly different from the control ($p < 0.05$). In terms of fermentation, this study employed breath methane testing in order to detect differences in colonic fermentation. Increased breath methane levels were found with fine wheat bran when compared with both the medium particle size and low fibre control treatments ($p=0.025$). The authors suggest that these findings point to increased fermentation, that is increased fecal butyrate concentrations which are known to be beneficial for mucosal health (Jenkins *et al*, 1999).

Similar findings in terms of increased stool bulk and fecal output were reported by Lewis and Heaton (1999) using inert plastic particles intended to mimic wheat bran. They did not find a significant difference in transit time between the “branlike flakes” and smaller granules (Lewis & Heaton, 1999). They did, however, find significant

changes in both groups with regards to improved stool form score, increased stool output and increased stool frequency (Lewis & Heaton, 1999).

Overall, research points to a significant increase in stool output and fecal bulking, even when finely ground fibre sources are employed (Jenkins *et al*, 1999; Lewis & Heaton, 1999). There also appears to be an effect of increased stool frequency (Lewis & Heaton, 1999) and increased colonic fermentation (Jenkins *et al,* 1999).

The delay in hunger and increased satiety brought on by a coarse dietary fibre could potentially be beneficial in weight reducing diets (Vincent *et al*, 1995). However, it could be detrimental in certain populations of children. In these instances, sources of finely ground dietary fibre may prove superior in the treatment of constipation.

2.6.3 The Treatment of Constipation with Dietary Fibre in Children

There are two trials using fibre supplements in constipated children that have been published. Both are double-blind, randomized controlled trials. The first of these studies used a supplement composed primarily of soluble fibre (Loening-Baucke *et al*, 2004) and the other a supplement composed primarily of insoluble fibre (Castillejo *et al*, 2006). Both of these products were added to other foods or beverages for consumption and no adverse events were reported. Loening-Baucke *et al* (2004) studied 31 chronically constipated children using a multi-centre (US and Italy) crossover design with 4 weeks per treatment period. The fibre source used was 100 mg/kg body weight glucomannan powder mixed with fluid. Glucomannan is a fibre gel polysaccharide composed of beta-1,4-linked D-glucose and D-mannose prepared from the tubers of the Japanese Konjac plant. Chronic functional constipation was defined as

occurring for six months or longer, difficulty or delay in defecation, duration of more than two weeks, and causing distress in the child (Loening-Baucke *et al*, 2004). Laxatives remained unaltered during the study period, although fecal impactions were cleared using enemas prior to study start, as well as at 4 and 8 weeks, if necessary. It is unclear in the study protocol whether or not a washout period was in effect.

The mean age of study participants was 7 years (± 2 years).This study included patients with encopresis (n=18). Encopresis is the term used to describe involuntary fecal soiling, although there is debate among experts on the terminology used to describe fecal soiling (Benninga *et al,* 2005).

Successful treatment was determined by a physician and was rated and defined as ≥ 3 BMs/week and ≤ 1 soiling episode/3 weeks with no abdominal pain (Loening-Baucke *et al,* 2004). Parental rating of progress, although subjective, was also assessed using a questionnaire. In both fibre treatment arms, stool frequency, stool consistency and soiling episodes showed statistical improvement (Loening-Baucke *et al*, 2004). Parental rating showed an improvement of symptoms in 68% of children while on the fibre treatment (Loening-Baucke *et al,* 2004).

The second study using a fibre supplement in children was done in 48 chronically constipated children, as assessed by the Rome II criteria. Study participants were randomized to the placebo or the cocoa husk supplement group and analysis was performed pre- and post-four week control/treatment period, respectively (Castillejo *et al,* 2006). The fibre source used for the treatment group was cocoa husk soluble powder and it was dissolved in 200 mL of whole milk (Castillejo *et al,* 2006).

Four groups of variables were analyzed by these researchers: 1) anthropometry, physical exam, routine lab measurements, 2) total and segmental colonic transit time, 3) evaluation of bowel movements and stool consistency with a diary, and 4) subjective evaluation from parents regarding efficacy of treatment. They found a trend towards an increase in transit time in the cocoa husk group compared to the placebo, as well as a significant increase in stool frequency in the treatment group (Castillejo *et al,* 2006). In terms of stool consistency, 42% of the treatment group participants observed hard stools at the end of the intervention period, compared to 75% of the placebo participants (Castillejo *et al,* 2006). Parental subjective ratings were also analyzed. A significant subjective improvement in stool consistency in the treatment group was observed by parents.

Overall, it appears that increased dietary fibre intake is helpful in the treatment of many cases of pediatric constipation. There also may be a role for dietary fibre in the prevention of constipation, as indicated by the relationship between low dietary fibre intakes and increased risk of constipation, but further research is required to confirm these findings.

CHAPTER 3
RESEARCH METHODS

3.1 STUDY DESIGN

3.1.1 Participants

Eligible participants were between the ages of two and ten years and were identified by their parents as having a history of constipation and/or a history of abdominal pain in the previous twelve months. Organic causes for either condition were ruled out prior to study participation. A letter was sent to the participants' physicians indicating their study participation. Participants on a previously established regimen of laxatives were permitted to participate in the study and were requested to maintain a consistent dose of the laxatives throughout the study period. A detailed questionnaire at study start included information on medication and supplement use.

Participants who experienced encopresis in the previous month, with a history of milk allergy, intolerance or sensitivity, with a history of allergy to peas, with celiac disease, or who required an enema to resolve fecal impaction one week or less prior to the start of the study were excluded. Furthermore, participants diagnosed with constipation of organic origin (e.g. Hirschsprung disease, mental deficiency, neurological abnormalities, chronic debilitating disease, psychiatric illness, previous intestinal surgery), participants with a metabolic disease (e.g. renal insufficiency, hypocalcemia, hyperkalemia) and those using medications that affect gastrointestinal

motility (e.g. anticonvulsants, imipramine) were excluded from the study. Patients were healthy, other than issues with constipation.

Approval for the study was granted by the Biomedical Research Ethics Board at the University of Saskatchewan, Saskatoon, Saskatchewan (Appendix 1). Informed consent was obtained by the caregiver (Appendix 2.1) and assent was sought from children seven to ten years of age (Appendix 2.2).

3.1.2 Recruitment

Participant recruitment consisted of children two to ten years of age with a history of constipation in the previous twelve months. Constipation was defined according to the Canadian Pediatric Society criteria, "Bowel movements that happen less often than usual, are hard and dry, and/or are difficult or painful to pass". Parents identified their child as having constipation based on this statement. Participants were recruited through advertisements in a local community newspaper (Appendix 3.1) and posters displayed at local daycare centres (Appendix 3.2). Posters were displayed from May-August 2007 and newspaper ads were placed in August 2007, October 2007 and January 2008. Participants were enrolled and completed the study between October 2007 and May 2008.

Interested parents had the option of calling or sending an email to the investigator for more information. A copy of the study consent form and a brief written explanation was either mailed or emailed to all parents who contacted the investigator. The parents of twenty-six children received information about the study either verbally

over the phone and/or in written form (mail or email). Of these, seventeen participants were enrolled in the study.

3.1.3 Random Assignment

The trial was designed as a randomized, double-blind, placebo-controlled, cross-over study. Eligible participants began with either the placebo or fibre treatment period as determined by a computer-generated randomization list, which was controlled by an undergraduate student in the College of Pharmacy and Nutrition, University of Saskatchewan. Each sequence was a total of three weeks and was not revealed to the researchers, the participants or the caregivers until all participants had completed the study protocol.

3.1.4 Study Protocol

Participants and caregivers were advised of the study protocol at the start of the study. The participant and caregiver were provided with a three-week supply of the supplement and snack foods coded as A or B, depending on their allocated sequence. Following unblinding, it was determined that the "A" snacks and supplements were the fibre treatment, whereas the items labeled "B" were placebo.

Participants were requested to consume one package of inulin supplement (5 g per day: Fruitafit® CLR, Sensus America LLC, Monmouth Junction, NJ, USA) or placebo (5 g of non-resistant maltodextrin: Casco, Globe Plus 18 DE – Maltodextrin, Etobicoke, ON, Canada). The supplement was to be mixed with a beverage. They would also consume two servings of the study snacks, with or without added pea hull

fibre (1.8-3.4 g of fibre per serving: Best Pea Fibre, Best Cooking Pulses, Inc., Portage la Prairie, MB, Canada) on a daily basis. At the three-week visit, participants were crossed over to the other treatment period. All leftover snacks and packages of supplement were returned at that time.

The snack foods were created and developed by a Product Development Specialist (College of Agriculture and Bioresources, University of Saskatchewan) and Research Assistant (College of Pharmacy and Nutrition, University of Saskatchewan). The recipes were prepared by the same technician (Research Assistant, College of Pharmacy and Nutrition, University of Saskatchewan) for all snack foods.

The placebo recipes did not contain added pea hull fibre (see Appendix 4.1). The fibre-supplemented recipes contained pea hull fibre in addition to the other ingredients (see Appendix 4.2). In some recipes, including the Chocolate Chip Cookies, the Raisin Honey Chews, the Cheese Sticks, and the Honey Graham Crackers, the pea hull fibre substituted for part of the wheat flour. Questionnaires were administered to caregivers to evaluate the eligibility of the child (Appendix 5.1). Mid-point and post-study questionnaires were also administered to capture the global assessments of caregivers as to whether they perceived that their child was doing better in the first or second treatment period (Appendix 5.2 and 5.3).

Participants and their caregivers had the opportunity to examine the information outlining the trial, as well as the consent information. Assent was sought for children seven years of age and up, as well as consent from the caregivers of all children. Once a consent form was signed, the researcher randomized the participants to begin with the "A" or "B" sequence (fibre treatment or placebo). Participants were permitted to taste-

test the study snacks to determine their preference. Participants were provided with a study diary (Appendix 5) and appropriately labeled test foods and supplements.

Healthy eating, physical activity and adequate fluid guidelines were discussed with all caregivers at the study start and Eating Well with Canada's Food Guide was provided as a resource. The participants were weighed and measured at the first visit and subsequently at the three-week and six-week visits.

Participants and/or caregivers were required to keep a record in the study diary of the supplement and snacks consumed daily. They were also requested to record the number of bowel movements, the presence or absence of abdominal pain, and the consistency and appearance of the stool (Bristol Stool Form Scale). This scale has been validated as an indicator for intestinal transit time in healthy adults (Lewis & Heaton, 1997). Caregivers were also requested to record food intake for three days for each three-week study period (total of six days per participant).

The Bristol Stool Form Rating scale is based on a seven-point picture and word description of stools (Table 3.1). It has been used in research as an indicator of transit time.

Table 3.1 Description of Bristol Stool Rating Scale

Rating	Description	Transit Rate
1	Separate hard lumps like nuts	Extremely slow
2	Sausage shaped but lumpy	Very slow
3	Like a sausage but with cracks on surface	Normal
4	Like a sausage	Normal
5	Soft blobs with clear-cut edges	Fast
6	Fluffy pieces with ragged edges	Very fast
7	Watery	Extremely fast

Adapted from Lewis & Heaton, 1997.

Compliance to the study protocol and acceptability of the snack foods and fibre supplement were evaluated using the study diaries. Also, families were requested to return unused portions of food and supplement to help determine the accuracy of reported intakes.

Ingredient lists of the high-fibre foods used in the study were provided to all participants and their families following the conclusion of the study. Sample packages of both inulin and pea hull fibre, as well as the method of preparation of study snacks, was provided to all interested families. This allowed them to continue with treatment if they deemed it beneficial, although no follow-up was planned or carried out as to whether they continued to use the products.

3.2 DATA ANALYSIS

3.2.1 Sample Size Calculation

In a similar cross-over design study, clinical investigators suggested a sample size of twenty-six participants. This was based on $\alpha = 0.05$ (two-tailed test) and a power of 95% to detect a difference of 0.7 compared to 0.2 in attaining normal bowel movements in a cross-over design (Loening-Baucke, Miele, & Staiano, 2004). However, it should be noted that the current study used a different method of collecting data on stool frequency.

3.2.2 Statistical Analysis

All statistical analyses were performed using Microsoft Office Excel 2007 ®. The differences between the placebo and fibre treatment periods were analyzed for the study participants with the paired *t*-test, also called the repeated measures *t*-test, which is a within subject comparison of pre- and post-test scores.

A p-value of <0.05 (two-sided) was deemed to be statistically significant. To check for period effects, an independent *t*-test was used. Also, analysis of a possible effect of period order was examined using the independent *t*-test. Due to the stool frequency results following a normal distribution, parametric tests were applied to analyze the data. Also, in cross-over designs parametric analysis may be the preference (Senn, 2002).

3.2.3 Demographic Data

Demographic information for both the placebo and fibre groups was calculated as mean values with a range following randomization. Comparisons between groups were made with the independent *t*-test.

3.2.4 Questionnaires

The mid-point and post-study questionnaires included responses graded on a five-point Likert scale. Each response ranked between one (indicating an improvement) to five (indicating worsening). The response category, "A lot better" represented a score of one, "A little better" represented a score of two, "About the same" represented a score of three, "A little worse" represented a score of four, and a score of five was assigned to the response, "A lot worse".

3.2.5 Study Diary and Food Records

Stool frequency (number per 24-hour period) and abdominal pain (presence or absence) were labeled and entered into a spreadsheet. Stool frequency was compared between the fibre period and placebo period for all participants for weeks 2 and 3 separately and combined. The number of incidents of abdominal pain for each participant during each study period was compared. Differences for both measures were analyzed with the paired *t*-test.

Energy and dietary fibre intakes were analyzed to determine differences between the two study periods. The results were analyzed using The Food Processor (Food Processor for Windows, ESHA Research, Salem, OR, USA) and then final values were

entered into a spreadsheet. The nutrient information for inulin, pea hull fibre and maltodextrin was not found in the Food Processor database; therefore, the nutritional information for each product, as provided by the suppliers, was entered into the program.

Inulin was analyzed based on 1.6 kcal/g and 90 g of dietary fibre per 100 g of product. This includes 1.5 kcal/g from the fermentation of inulin in the colon and the resulting energy source (SCFA production) based on a review article (Carabin & Flamm, 1999) (see section 2.2.4). The remaining energy comes from the digestible carbohydrates (fructose, glucose and sucrose). The pea hull fibre was analyzed based on 0.58 kcal/g, which consists of 89.3 g of dietary fibre per 100 g of product. The energy is provided by a small amount of starch contamination of the fibre, as well as small amounts of protein and fat. Due to the insolubility of pea hull fiber and a lack of data on the energy yielded by pea hull fibre fermentation in the literature, current labeling does not include an energy value from dietary fibre. As a result, any potential energy yield from pea hull fibre fermentation could not be estimated in this study and a value of 0 kcal/g was assigned. Maltodextrin was analyzed based on 3.8 kcal/g of product as it did not contain any dietary fibre.

Intake of snacks was recorded in the study diary and this was used to measure acceptability/compliance. Snacks recorded as half or more consumed were included in the analysis. If a snack was recorded as 75% consumed, it was counted as one serving. Differences in acceptability between participants from one period to the next were compared using a paired *t*-test.

Intake of the supplement (inulin or maltodextrin) was also recorded in the study diary as an indicator of compliance. A minimum intake of half of the portion of supplement was required for inclusion in the analysis. An indication of 75% consumption was recorded as one full serving. Differences in compliance between participants from each period were compared using a paired *t*-test.

For both the snacks and the supplement, the treatment and the placebo groups were compared using a paired *t*-test. A non-significant finding indicates no difference between groups in terms of compliance.

3.3 OUTCOMES

The measures recorded included frequency of bowel movements, presence or absence of abdominal pain, dietary fibre intake (three-day food record for each period of study, consisting of two, non-consecutive weekdays and one weekend day), medications, supplements, stool frequency, stool form rating and anthropometry (body weight and height). The outcomes assessed included dietary fibre intake, stool frequency, presence or absence of abdominal pain, and changes in energy intake and in weight. The Bristol Stool Form Scale was used as a guide for estimating the intestinal transit rate (Lewis & Heaton, 1997).

The tolerance of the fibre supplement, inulin, and the snack foods fortified with pea hull fibre were evaluated by reports from parents and children on any side effects, for example, abdominal pain, bloating or gas. The efficacy of the fibre supplementation and fortification was evaluated based on changes in stool frequency, transit time and

abdominal pain in the last two weeks of each three-week treatment period, using the diary in addition to information from the participants and parents.

CHAPTER 4
RESULTS

4.1 STUDY PARTICIPANTS

4.1.1 Characteristics of Participants

Between October 2007 and May 2008, seventeen participants eligible to participate in the study were enrolled. Consent was obtained from the parents of all participants. Assent was obtained from children ≥ seven years of age (n=4). Thirteen participants completed both the placebo and treatment periods (see Figure 4.1 for a schematic of the participant flow in the study). The reasons for dropping out included the following: one participant moved, one became ill, one participant had a family crisis and one child associated the placebo (maltodextrin) with abdominal pain. Three of these children were randomized to receive the placebo first and one was randomized to receive fibre first. Data from these four children were excluded from the analysis. Data analysis included thirteen children with chronic constipation. These eight girls and five boys were 3.2-9.6 years old (mean: 5.6 ± 2.2 years). The characteristics of the study participants can be found in Table 4.1.

Figure 4.1 Participant Flow Diagram

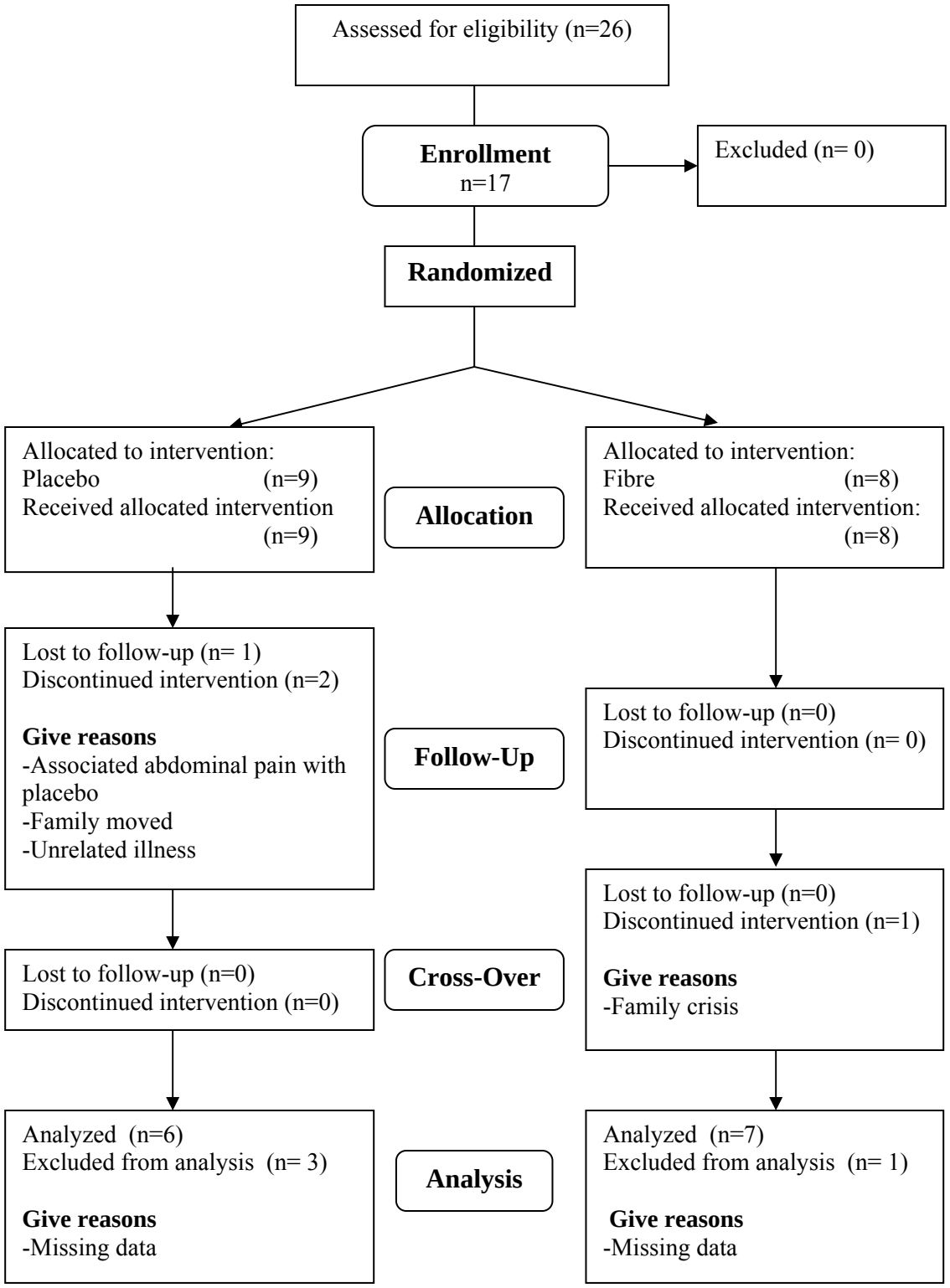


Table 4.1 Characteristics of Pediatric Study Participants by Group*

Case No.	Age	Gender	Laxatives	Daily dosage
Group A				
2	7.9	M	None	n/a
4	3.7	F	Lactulose	2 tbsp
5	3.8	F	None	n/a
7	5.6	F	None	n/a
8	5.1	F	None	n/a
10	3.5	M	Milk of magnesia	1.5-2 tsp
11	8.9	F	None	n/a
Group B				
1	7	M	Magnolax	1 tbsp
3	3.4	F	Lactulose	1-2 tsp
6	9.6	F	None	n/a
9	3.2	M	None	n/a
12	6.8	F	None	n/a
13	4.1	M	Magnolax; milk of magnesia	10 mL; 5 mL

*Group A refers to participants randomized to fibre/placebo sequence and Group B refers to participants randomized to the placebo/fibre sequence.

4.1.2 Laxative Use

Thirty-six percent (five of thirteen) participants were on laxatives but still experienced symptoms of constipation. Two participants (Cases 3 and 4) were on lactulose, which is a poorly absorbed disaccharide considered to be an osmotic laxative. Two additional participants were on milk of magnesia (Cases 10 and 13), although one of these (Case 13) and another participant (Case 1) were also on Magnolax. Milk of magnesia is a suspension of magnesium hydroxide, whereas Magnolax is in tablet form. Both are classified as saline osmotic laxatives.

4.2 TOLERANCE

There were no reports of significant side effects during the three-week placebo and three-week fibre treatment periods. One participant appeared to associate the maltodextrin supplement with abdominal pain and discontinued the study as a result.

One parent noted an increase in flatulence in her child during participation in the fibre treatment period (Case 3). However, it was indicated in the questionnaire that this did not appear to cause the child any discomfort or distress. This participant's intake of inulin supplement was measured at 85% over the three-week period and intake of study snacks was virtually nil.

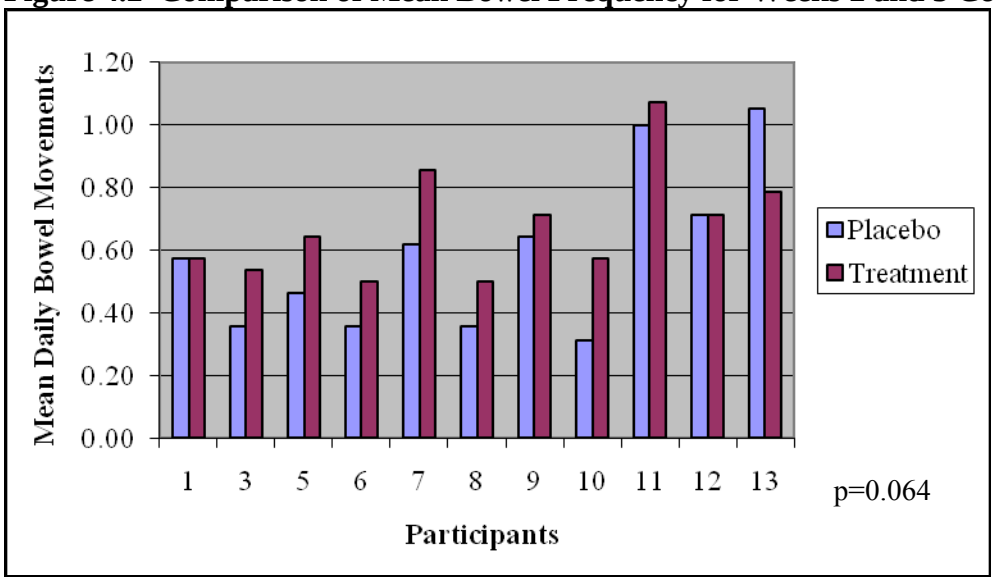
4.3 STOOL FREQUENCY

4.3.1 Mean Daily Stool Frequency

One participant did not record stool frequency for week two of the placebo period and week three of the treatment period. An additional participant did not record bowel movements during week two of the treatment period. Seven of eleven participants on fibre supplements had a significant increase in stool frequency compared to the placebo during week two of the study (mean = 0.74 ± 0.27 bowel movements per day vs. 0.53 ± 0.21, $p = 0.009$). Three participants reported no difference and one participant experienced decreased stool frequency during the fibre treatment period compared to the placebo. There was no significant difference ($n = 11$) during week three of the study between the treatment (mean = 0.64 ± 0.16) and the placebo groups (mean = 0.65 ± 0.35) ($p = 0.909$).

In examining weeks 2 and 3 combined, there was a trend towards an increased number of daily bowel movements during the treatment period compared to the placebo, but this did not reach significance (0.59 ± 0.26 vs. 0.68 ± 0.18, p = 0.064) (see Figure 4.2). Case 13 reportedly had diarrhea-type stools (see section 4.5). If this participant is excluded from the analysis of stool frequency on this basis, then the trend becomes significant (n=10, 0.54 ± 0.18 vs. 0.67 ± 0.22, p=0.002).

Figure 4.2 Comparison of Mean Bowel Frequency for Weeks 2 and 3 Combined



Of those parents perceiving a change in stool frequency in their child, four of eleven perceived a decrease in stool frequency during the placebo compared to three of eleven during the fibre treatment period.

4.3.2 Weekly Stool Frequency

Stool frequency by week was also examined. None of the participants consistently had fewer than three bowel movements per week throughout the placebo period, which is one of the criteria for the diagnosis of pediatric constipation according

to the Rome III criteria. One participant (Case 10) had two consecutive weeks of two BMs per week during the placebo period but the Rome III criteria require at least a two-month duration of symptoms with an additional criterion consistently met weekly (Hyman *et al*, 2006). On this basis, none of the participants would meet the Rome III criteria unless they fulfilled one of the other criteria, which could not be investigated in this study, for example, the presence of a large fecal mass in the rectum.

4.4 ABDOMINAL PAIN

Nine of thirteen participants experienced abdominal pain during the study. There was no significant difference in the mean number of reported incidents of abdominal pain between the fibre treatment period (mean = 5.3 ± 3.4 incidents) and the placebo period (mean = 3.6 ± 2.5 incidents) ($p = 0.129$).

Some parents reported abdominal pain as a symptom (six of thirteen) during the study. Of those participants experiencing abdominal pain, four of six identified increased abdominal pain during the placebo, compared to two of six during the fibre treatment period, but this difference did not reach significance ($p = 0.490$).

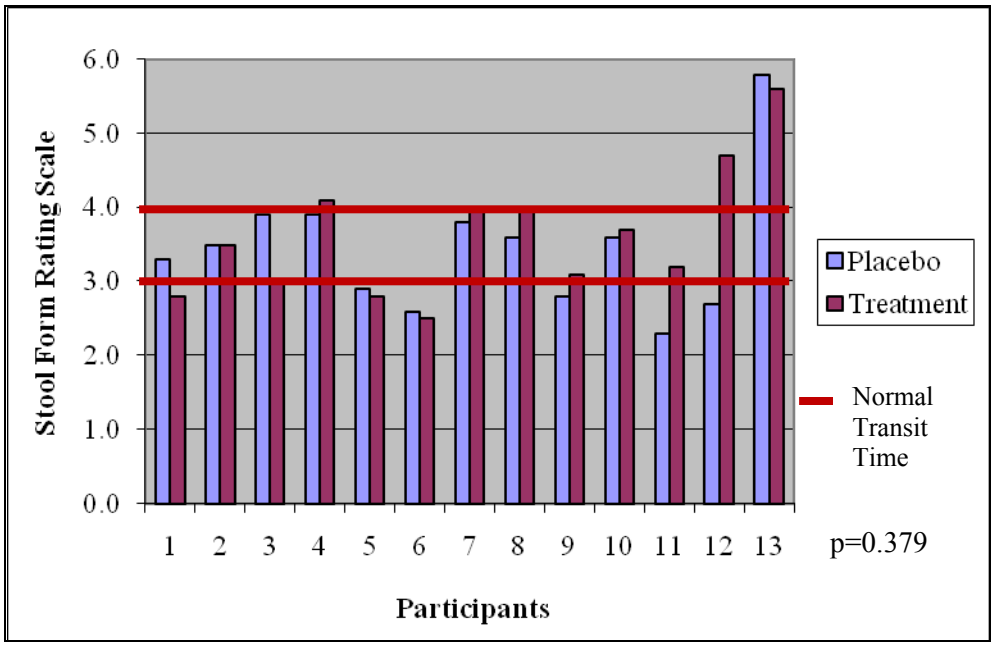
4.5 STOOL FORM RATING SCALE

A rating of three to four is considered normal transit time based on the Bristol Stool Form Rating Scale (Lewis & Heaton, 1997). No significant difference in transit time was found between the study periods ($p = 0.379$). The average rating during the fibre treatment period was 3.6 ± 0.9 and during the placebo period it was 3.4 ± 0.9, which was within the normal range of 3.0-4.0 (Figure 4.3). The majority of participants

had a normal transit time during the placebo period with the exception of Cases 6, 11 and 12.

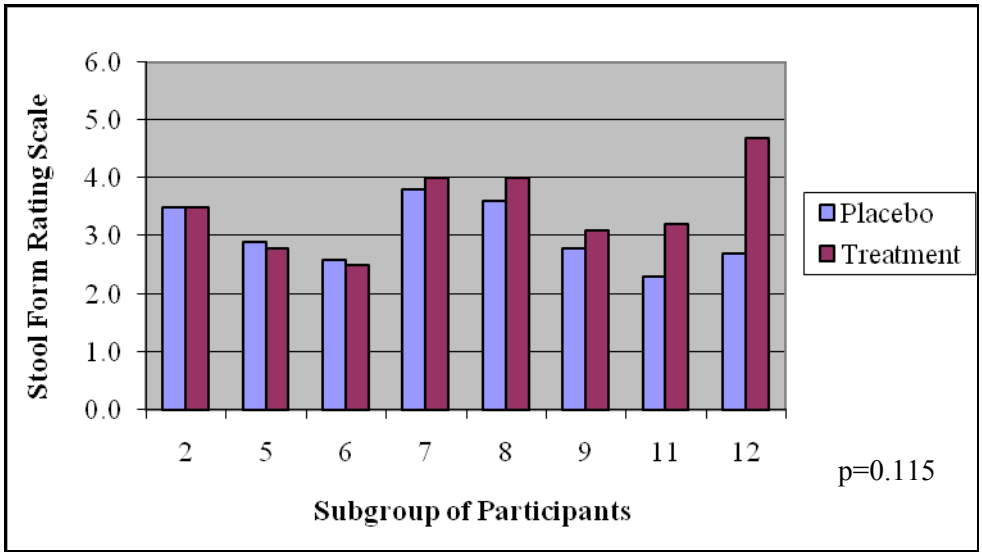
One participant (Case 13) recorded ratings of 5.6 and 5.8 for the fibre treatment and placebo periods, respectively, which is actually considered to be rapid transit time, more in keeping with diarrhea-type stools. Exclusion of this participant from the analysis did produce a significant difference between the two groups (p = 0.002).

Figure 4.3 Comparison of Stool Form Rating Scale For Placebo and Treatment Periods



The study periods were also analyzed with the exclusion of the participants on laxatives. In this subgroup, no significant differences were found in the estimated transit time from one study period to the other (Figure 4.4). The mean stool form rating during the treatment period was 3.5 ± 0.7, whereas it was 3.0 ± 0.5 during the placebo period (p = 0.115).

Figure 4.4 Comparison of Stool Form Rating Scale in a Subgroup of Participants Not on Concomitant Laxatives



4.6 PARENTAL PERCEPTIONS

4.6.1 Physical Changes

Some parents (four of thirteen) identified changes in how their child felt physically during the study. Three of those four reported a perceived improvement in how their child felt physically during the fibre treatment period compared to the placebo period.

4.6.2 Emotional and Social Changes

Only two participants experienced emotional changes, as identified by their parents. In both cases, an improvement was identified by parents during the fibre treatment period compared to the placebo. One participant was reported to have an improvement in social interactions during the fibre treatment period.

4.7 COMPLIANCE

4.7.1 Snack Foods

Compliance with the study snacks was the same for both the placebo and the fibre-fortified snacks (74% compared to 77%, respectively, n = 12, p = 0.328). One participant (Case 9) consumed virtually no snacks throughout both study periods and so was excluded from this analysis. The mean intake of snacks during the placebo period was 1.6 snacks per day and 1.7 snacks per day during the treatment period (n = 12; range of 0-3 snacks per day).

4.7.2 Supplement

The supplement was consumed equally as often in both periods of the study (p = 0.412) with a compliance of 91% for inulin and 94% for maltodextrin. Furthermore, there were no differences in consumption when participants were compared from one study period to the other (sequence 1: fibre/placebo: p = 0.176; sequence 2: placebo/fibre: p = 0.983).

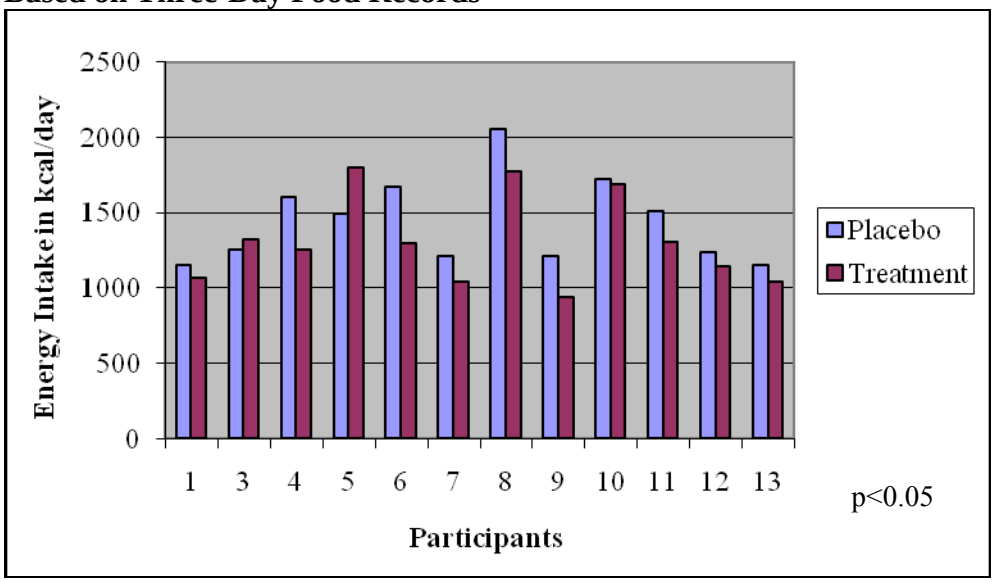
4.8 FOOD RECORD ANALYSIS

4.8.1 Energy Intake

Energy intake was different for the placebo period compared to the fibre treatment period for all three days recorded (see Figure 4.5). One participant (Case 2) was excluded from the analysis due to missing data (food intake for one of three days during the fibre treatment period was not recorded). The mean intake of energy during

the treatment period was significantly lower at 1307 ± 296 kcal/d, compared to the placebo period with a mean intake of 1441 ± 285 kcal/d (n = 12, p = 0.035).

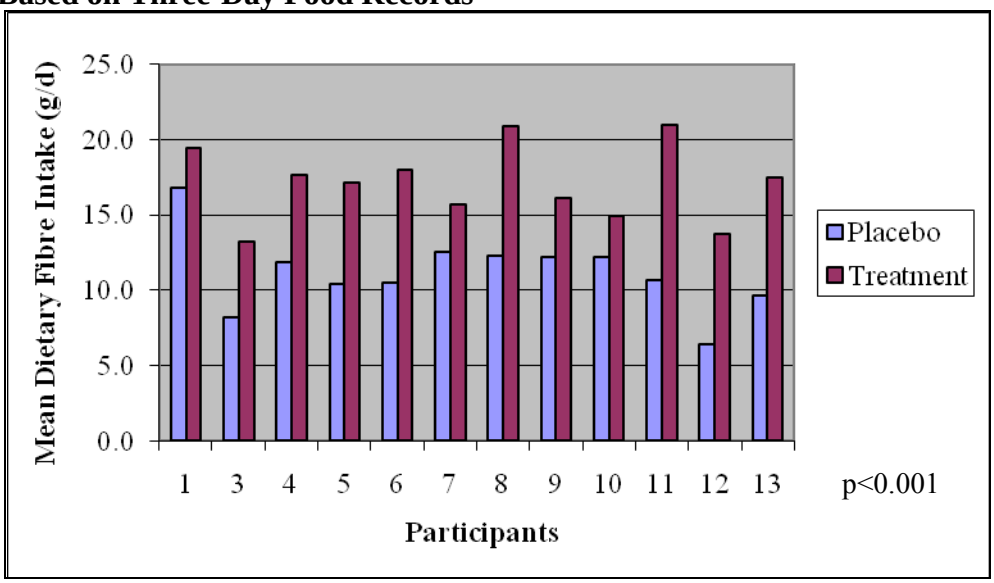
Figure 4.5 Comparison of Energy Intake During Fibre Treatment and Placebo Based on Three-Day Food Records



4.8.2 Dietary Fibre Intake

As revealed by the food records, the mean dietary fibre intake for the treatment period was significantly higher than the dietary fibre intake during the placebo period (see Figure 4.6) (n = 12, 17.1 ± 2.5 g/d vs. 11.1 ± 2.6 g/d, p<0.001). During the placebo period, the snacks provided a mean of 1.0 ± 0.8 g/d of dietary fibre compared to 3.7 ± 1.2 g/d during the fibre treatment period (p<0.001). The fibre treatment group consumed an average of 4.2 ± 0.9 g/d from inulin, whereas maltodextrin did not provide any fibre during the placebo period as it is not considered to be a source of dietary fibre.

Figure 4.6 Comparison of Dietary Fibre Intake by Study Participant and Period Based on Three-Day Food Records



There was no significant difference in the amount of dietary fibre provided to participants by the rest of the diet. The placebo group consumed 9.8 ± 2.6 g/d compared to 9.4 ± 2.1 g/d ($p = 0.584$) for the treatment group exclusive of the fibre provided by the pea fibre and inulin. Table 4.2 below provides a comparison of usual intakes of dietary fibre for Canadian children compared to the study participants. In the current study, children 1-3 years old had similar intakes compared to the survey data obtained for Canadian children. However, the older children 4-10 years in the current study had a trend towards lower mean dietary fibre intakes when compared with the survey data.

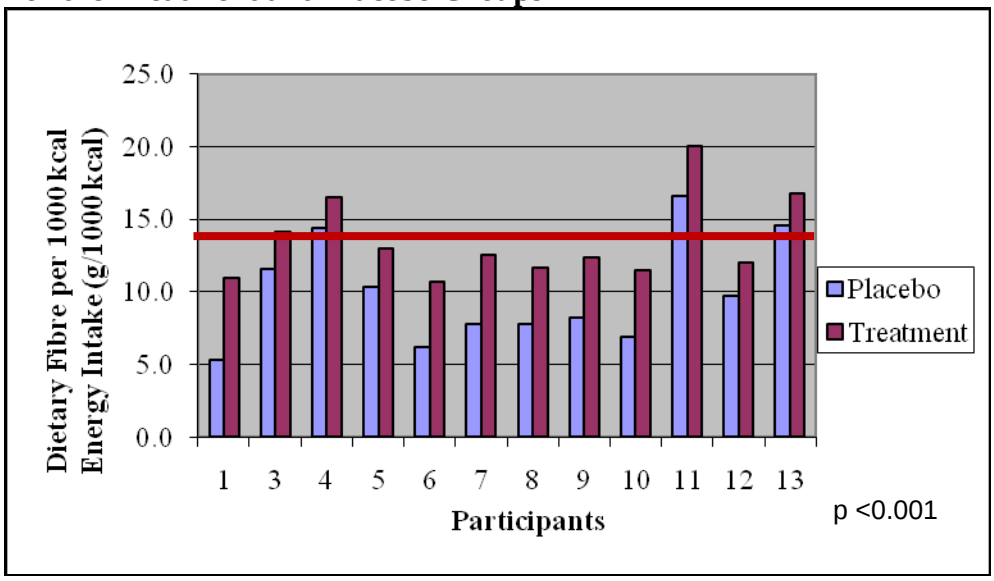
Table 4.2 Dietary Fibre Intakes (g/d) of Canadian Children* Compared With Study Participants by Age Group

Age (years)	n*	Mean 2004 Data*	n	Mean Study Data (Placebo Period)
1-3	2117	10.2	5	10.0
4-8	3235	13.5	5	12.1
9-13 (female)	1980	14.4	2	12.2

**Statistics Canada, Canadian Community Health Survey, Cycle 2.2, Nutrition (2004) – Share File*

When fibre intakes were examined on a per 1000 kcal of energy basis, the fibre treatment group had a significantly greater intake (mean intake = 13.2 ± 2.9 g/1000 kcal) than did the placebo group (mean intake = 9.5 ± 3.6 g/1000 kcal, $p<0.001$). The fibre treatment group neared the recommended AI for dietary fibre of 14 g/1000 kcal (indicated by the red line in Figure 4.7).

Figure 4.7 Comparison of Dietary Fibre Intake per 1000 kcal of Energy Intake For the Treatment and Placebo Groups



As the recommendation for dietary fibre is set as an AI, it can be viewed in terms of mean intakes. Four participants (Cases 3, 4, 11 and 13) had a mean intake of ≥14 g of dietary fibre per1000 kcal of energy intake during the treatment period. Three of the four participants had intakes at this level during the placebo period as well, although the intakes were at least two grams per day higher during the fibre treatment period for all four participants based on the data from the three-day food records.

4.9 ANTHROPOMETRIC DATA

The study participants had their weight and height measured at the study start, mid-point (cross-over) and end of the study (see Table 4.3). Data for one participant were missing (Case 2- measurements not taken at mid-point of study). The BMI (body mass index) for each participant at each time point was measured using the standard equation of BMI = weight (kg)/height (m)^2. The BMI values were then plotted on the 2000 CDC (Centres for Disease Control) Growth Charts. The differences in BMI following the fibre treatment and placebo periods were compared for each participant. For example, the weight and height of a participant who started on the fibre treatment were taken at baseline and after three weeks. The difference in BMI between the baseline and mid-point of the study was then calculated. For the placebo period, the change in BMI from the mid-point to end of the study would be calculated for this participant. In this manner, the changes in BMI for each participant were compared for each period of the study to determine if there were significant differences between them. This would help to indicate whether participants potentially gained more weight compared to height while on the placebo treatment compared to the fibre treatment.

Table 4.3 BMI Data for Study Participants

Case No.	BMI #1	BMI #2	BMI #3	Difference during Fibre Treatment	Difference during Placebo Period
1	19.5	20.7	20.6	0.1	1.0
3	16.2	16.7	16.4	-0.3	0.9
4	16.8	16.8	16.4	0.4	-0.4
5	15.9	16.6	16.5	0.6	-0.3
6	28.4	28.1	27.7	-0.3	0.1
7	14.7	14.4	14.6	-0.2	0.3
8	18.1	17.8	18.2	-0.4	0.4
9	16.1	16.1	15.8	-0.3	-0.2
10	16.9	16.9	16.6	0.3	-0.3
11	18.1	18.0	18.5	-0.1	0.6
12	13.9	13.9	14.3	0.7	-0.2
13	16.1	16.5	16.4	-0.1	0.8

Based on the article "The Use and Interpretation of the CDC Growth Charts" (2000), the BMI for all participants was within the normal range (5^{th}-85^{th} percentile) with the exception of three (Cases 1, 6 and 10). The ages of these participants were 7, 9 and 3, respectively, and Cases 1 and 10 were male, whereas Case 6 was female. All three of these participants had a BMI $\geq 95^{th}$ percentile, which places them in the overweight category based on the nutritional risk indicator (CDC, 2000). None of the participants was classified as underweight. Additionally, it was found that there were no significant differences in the change in BMI between participants for the fibre and placebo periods ($n = 12$, mean = 0.04 and 0.23, respectively, $p = 0.399$).

Due to growth in children, changes in weight and height would be expected. However, in the short time frame of this study, it would not be expected that any significant changes in BMI would occur, as children tend to grow proportionately in height and weight. Also, the BMI of boys and girls appears to be lower in children under the age of ten compared to adolescents.

4.10 PERIOD EFFECT

All major parameters were analyzed to determine if there was a period effect, that is, whether or not there was a difference in the findings for participants who started on the placebo treatment versus those who started on the fibre treatment. Given that random allocation was used, it would not be expected that a period effect would be found (Senn, 2002). This was true in this study for the following: stool frequency, stool consistency, dietary fibre and energy intake, and compliance, as all of these resulted in non-significance using the independent *t*-test.

CHAPTER 5
DISCUSSION

5.1 DISCUSSION

This study demonstrated that dietary fibre fortification and supplementation can significantly increase the overall dietary fibre intake of children. Inulin supplementation was an acceptable method of adding dietary fibre to beverages, and fortification with pea hull fibre was an acceptable method of adding dietary fibre to snack foods. The addition of fibre to snack foods and beverages may provide a means to reduce their energy density. Finally, an increase in dietary fibre intake in children with mild constipation may not increase stool frequency and normalize intestinal transit time, particularly if stool patterns are within the normal range prior to increased dietary fibre intake.

Because of a lack of data, the Dietary Reference Intake for dietary fibre is set as an Adequate Intake (AI) based on intake levels estimated to be adequate in healthy people. In the case of dietary fibre, it is based on the observed amount shown to be protective against coronary heart disease (Slavin, 2004). It is not known what level of intake is required to promote adequate laxation.

The intake of dietary fibre for most children falls short of recommendations. The nutrient intakes of Canadian children were assessed in 2004 through the Canadian

Community Health Survey. It was found that 1-3 year old children (n = 2117) consumed a mean of 10.2 g/day of dietary fibre, whereas 4-8 year old children (n = 3235) consumed a mean of 13.5 g/day (Health Canada, 2006). This is a similar level of intake to the study group during the placebo period (11.1 g/day). The AIs for the age groups mentioned are 19 and 25 g/d, respectively. However, current data do not include functional fibre sources. Also, it is unknown how much functional fibre an average diet contains, although estimates for inulin and oligofructose in the U.S. are in the range of 1-4 g/day compared to 3-11 g/day for Europeans (Van Loo, 1995). Data from the CSFII (1994-1996) in the U.S. indicate an average intake of 2.6 g/day for inulin and 2.5 g/day for oligofructose (Moshfegh, Friday, Golman, & Chug Ahuja, 1999). Inulin has been added to many foods in Europe and North America over the last decade, and it has become widely available as a fibre supplement. It would be expected that these intakes have increased substantially but this data is not yet available.

The acceptance of the inulin supplement was particularly good among the participants. In most cases, it was dissolved in milk, chocolate milk or apple juice. In a few cases, when parents did not blind the child to supplementation of her beverage, she had a higher tendency to say she did not like it. The intake of snack foods was less than that of the inulin supplement. However, two servings of the snack foods were required daily compared to one serving of the inulin supplement. Other reasons for the decreased intake of snacks may have been related to the smaller selection of choices relative to what participants were accustomed to, or the replacement of usual, favourite snacks with study snacks. There were no stated concerns with the flavour of either the placebo or fibre-fortified snacks. This might be due to the fact that it was not necessary to

"blind" the child to the addition of the fibre or placebo into the food/beverage and may point to an advantage of having fibre-containing food and beverages on the market.

The epidemiological evidence for the prevention of obesity through higher dietary fibre intakes is reportedly strong (Slavin, 2004). There is a known gap between actual intakes of dietary fibre in children and the recommended amounts (Kranz et al, 2005). The current study found that energy intakes were significantly lower during the fibre treatment period of the study as compared to the placebo or "regular diet" period. This may occur through the "displacement" of energy dense ingredients such as sugar and fats, which may provide another potential application for the addition of fibre sources such as pea hull fibre and inulin to snack foods and beverages.

It should be noted that the fermentation of the fibre sources in question may have yielded additional energy. This is due to the fact that the SCFAs produced by fermentation are absorbed by colonocytes as an energy source with an estimated yield of 1.5 -2.5 kcal/g (Otten *et al*, 2006). On the other hand, it is thought that SCFAs have a direct effect on the regulation of satiety, thereby decreasing overall energy intake (Pereira & Ludwig, 2001). This may result in a negative energy balance if overall intake decreases compared to non-fermented carbohydrate sources. Energy provided by inulin fermentation was included in the analysis (1.5 kcal/g); however, it was not for pea hull fibre, as no data is available on the energy yield of pea hull fibre fermentation.

The results of this intervention are unique as this is the first time that two sources of dietary fibre have been used concurrently to increase dietary fibre intake in constipated children. Studies in adults have been completed with each type of fibre. One study using finely processed pea hull fibre (mean dietary fibre fortification = 3.1 g/d)

added to usual foods in a population of elderly patients found a significant increase in stool frequency (n = 114, 18.7 ± 9.4 BMs/month at baseline versus 20.1 ± 9.6 BMs/month during the fibre treatment, $p<0.05$) (Dahl *et al*, 2003). Interestingly, this study found an even larger difference in the sub-group of patients who had the lowest frequency of bowel movements (n = 17, 8.8 ± 1.0 BMs per month at baseline compared to 12.6 ± 3.8 BMs/month during the fibre treatment) (Dahl *et al*, 2003). The current study is particularly interesting in light of the lack of significant differences in stool frequency between the placebo and the fibre treatment groups, despite the significant increase in dietary fibre consumed.

The Rome III criteria for the diagnosis of pediatric functional constipation require as part of the diagnosis a bowel frequency of less than three BMs per week. It is interesting to note that none of the study participants consistently reported two or fewer weekly bowel movements during the placebo period of the study. Although parental perception indicated the participants were constipated, it is possible that their symptoms would not be deemed clinically significant with the use of a more strict definition such as Rome III. In this study, the other criteria associated with Rome III were not examined so it is unknown whether these participants would have fulfilled any of the other criteria, thereby meeting the diagnostic criteria for functional constipation. Further to this, the use of such a definition would possibly have provided a more homogeneous group of participants but would have required the participation of a closely involved physician. These children appear to have had normal transit time based on the Bristol Stool Form Scale, which would further put into question whether or not all study participants were in fact constipated.

Dietary fibre sources vary greatly and each type has its own physiological effects, which are not always studied in great detail. Prebiotics such as inulin have been studied more extensively than some other sources of fibre. In Canada, for example, a so-called "novel source" of fibre, such as pea hull fibre, must be proven to be safe and to have a physiological effect in order for it to be permitted for use as an ingredient in food (CFIA, 1996). Both pea hull fibre and inulin have been approved for such use.

Intervention studies have shown that inulin increases stool weight and thereby increases stool frequency, and the range of dosages used in research have varied from 5-15 g/day (Roberfroid, 2002). The daily inulin dose in this study (5 g weight = 4.5 g of fibre) was at the lower end of this scale due to the additive effect of using two fibre sources. As the inulin and pea hull fibre were well tolerated by the study participants, an increased intake of inulin may have produced a more significant effect on stool patterns.

Stool output was not tracked in this study, although fecal bulking capacity of the inulin supplement and pea fibre fortified snack foods can be estimated using previous research. Bulking index has been used to compare the variable bulking capacities of indigestible carbohydrates in rat and human studies. The bulking index is measured as either an increase in fecal wet or dry weight in grams per gram of added indigestible carbohydrate in the diet (Nyman, 2002). For inulin, studies in humans have demonstrated a bulking index of 1.5 (based on fecal dry weight) (Den Hond, 2000; Nyman, 2002). In the current study, 4.5 g of dietary fibre from inulin were to be consumed daily; multiplied by the bulking index of 1.5, this would result in a bulking capacity of 6.75 g per day.

Only rat studies are available for estimation of the bulking capacity of pea fibre and results should, therefore, be interpreted with caution. A bulking index of 0.2 g (based on fecal wet weight) was calculated by Hansen, Bach Knudsen, & Eggum (1992), but the pea fibre in their study was obtained from cotyledon cell wall fibre rather than hull fibre, which would have different characteristics.

The diet was not controlled in this study and this may account for the lack of a significant effect on stool frequency of the fibre sources used, namely inulin and pea hull fibre. For example, one parent stated that for their young child, the study snacks were sometimes so filling that their child's fruit intake was affected. In the case of young children, it may be that fibre added to a beverage, rather than provided as a snack food, would have less impact on overall intake of plant-based foods. Plant-based foods such as fruits, vegetables and whole grains are recognized as containing many other beneficial nutrients in addition to dietary fibre.

Although some of the study participants were using concomitant laxatives, it does not appear likely that these impacted the results to any great degree, as they had been on this treatment for some time and were requested to maintain the same therapy throughout the study period. Also, for parameters such as stool frequency and transit time measured in this study, secondary analysis of the data with exclusion of participants on laxatives did not result in significant findings.

The laxative lactulose has a similar physiological effect as does dietary fibre, as it is a poorly absorbed disaccharide that is rapidly fermented in the large intestine. Although it is not currently classified as a dietary (functional) fibre, one study included 6 g lactulose in comparison with 20 g of pectin or cellulose in a study protocol

examining differences in fermentation in men (Chinda *et al*, 2004). For the two study subjects using lactulose, they received a range of 3-20 g of lactulose. This would appear to be significant doses, which could mean that the intestinal microflora had reached a certain threshold in terms of bifidogenicity and fermentation and that they would not have experienced further benefits from the inulin supplementation.

An important advantage of the use of dietary fibre supplements and fibre-fortified foods is that it is viewed by parents as less "medical", with less chance of their child's bowel becoming used to it, such as with an osmotic laxative like lactulose. Many parents try to balance the potential effects of medication by using laxatives only when their child is symptomatic, which often results in a cycle of normal bowel movements and constipation. This could perhaps be explained by the fact that parents score their children worse in terms of quality of life (QOL) than constipated children themselves do. Clarke *et al* (2007) demonstrated that the parents of children with slow transit constipation (STC) reported a significantly lower QOL score than did their children. On the other hand, parents of controls scored similar QOL scores to their children's (Clarke *et al*, 2008). This may be related to the fact that there is often a family history of constipation and parents may be projecting their own experiences onto their child (Clarke *et al*, 2008).

There are a few notable limitations in the current study. The small sample size indicates that caution must be exercised with the interpretation of results, although many fibre studies have small sample sizes of about 10-12 healthy individuals. Also, two fibre sources were investigated in this study, which have been studied in adults but not in the pediatric population. Due to this it is unclear if the effects occurred as a result

of one or the other fibre sources. Further to this, additional measures could be used to better assess some of the parameters such as the quality of life of children experiencing constipation and analysis of stool weight and bacterial content. In spite of the aforementioned limitations, the objectives of the study were met, which provides a basis for future research into the effects of these fibre sources on childhood constipation.

Most researchers would agree that in terms of public health initiatives, recommendations should focus on an increased consumption of dietary fibre through plant-based foods such as vegetables, fruits and whole grains. It has been shown in previous studies that nutrient density and hence the quality of the diet improves with increasing dietary fibre intake in children. However, it has also been demonstrated that there are numerous barriers to this approach including lack of appetite in constipated children, low overall intake of high-fibre foods and lack of appeal of many high-fibre snack foods available in the market. For children experiencing constipation, a plant-based diet in addition to supplements and/or snack foods fortified with fibre may be a more effective approach to help them achieve their goal of increasing dietary fibre intake.

5.2 CONCLUSION

To summarize, this study showed that dietary fibre intake in children can be increased by means of fortification and supplementation. Also, it has provided some evidence for the reduction of energy in snack foods and beverages by the addition of dietary fibre. Finally, inulin and pea hull fibre are well tolerated and accepted means of increasing dietary fibre intake in children with constipation.

5.3 FUTURE RESEARCH

The results of this study are encouraging in that a larger randomized control trial would be warranted to examine the effects of fibre supplementation and fortification on childhood constipation. The protocol of future studies would be enhanced by the provision of the fibre sources separately and in combination to determine the optimal treatment, to use defined criteria for the diagnosis of constipation such as the Rome III criteria, and to better assess the quality of life issues of these children with a validated tool such as the Pediatrics Quality of Life Inventory (PedsQL™). Future research could also examine the role of laxatives in combination with the fibre sources for hard-to-treat cases of childhood constipation.

REFERENCES

Aggett, P. J., Agostoni, C., Axelsson, I., Edwards, C. A., Goulet, O., Hernell, O., et al. (2003). Nondigestible carbohydrates in the diets of infants and young children: A commentary by the ESPGHAN committee on nutrition. *Journal of Pediatric Gastroenterology & Nutrition, 36*(3), 329-337.

Akinbami, F. O., Erinoso, O., & Akinwolere, O. A. O. (1995). Defaecation pattern and intestinal transit in Nigerian children. *African Journal of Medicine and Medical Science, 24(*4), 337-41.

Amendola, S., De Angelis, P., Dall'oglio, L., Di Abriola, G. F., & Di Lorenzo, M. (2003). Combined approach to functional constipation in children. *Journal of Pediatric Surgery, 38(*5), 819-823.

Arhan, P., Devroede, G., Jehannin, B., Lanza, M., Faverdin, C., Dornic, C., *et al*. (1981). Segmental colonic transit time. *Diseases of the Colon and Rectum, 24*(8), 625-629.

Baker, S. S., Liptak, G. S., Colletti, R. B., Croffie, J. M., Di Lorenzo, C., Ector, W., *et al.* (1999). Constipation in infants and children: Evaluation and treatment. A medical position statement of the North American Society for Pediatric Gastroenterology and Nutrition. *Journal of Pediatric Gastroenterology and Nutrition, 29*(5), 612-626.

Benninga, M., Candy, D. C., Catto-Smith, A. G., Clayden, G., Loening-Baucke, V., Lorenzo, C. D., *et al*. (2005). The Paris consensus on childhood constipation terminology (PACCT) group. *Journal of Pediatric Gastroenterology & Nutrition, 40*(3), 273-275.

Bloom, D. A., Seeley, W. W., Ritchey, M. L., & McGuire, E.J. (1993). Toilet habits and continence in children: An opportunity sampling in search of normal parameters. *Journal of Urology, 149*(5), 1087-1090.

Bode, L. (2006). Recent advances on structure, metabolism, and function of human milk oligosaccharides. *The Journal of Nutrition, 136*(8), 2127-2130.

Borowitz, S. M., Cox, D. J., Tam, A., Ritterband, L. M., Sutphen, J. L., & Penberthy, J. K. (2003). Precipitants of constipation during early childhood. *Journal of the American Board of Family Practice, 16*(3), 213-218.

Bosaeus, I. (2004). Fibre effects on intestinal functions (diarrhoea, constipation and irritable bowel syndrome). *Clinical Nutrition Supplements, 1*(2), 33-38.

Bouchoucha, M., Devroede, G., Arhan, P., Strom, B., Weber, J., Cugnenc, P.-H., *et al.* (1992). What is the meaning of colorectal transit time measurement? *Diseases of the Colon and Rectum, 35*(8), 773-782.

Brand-Miller, J.C., & McVeagh, P. (1999). Human milk oligosaccharides : 130 reasons to breast-feed. *British Journal of Nutrition, 82*(5), 333-335.

Brandt, L. J., Prather, C. M., Quigley, E. M., Schiller, L. R., Schoenfeld, P., & Talley, N. J. (2005). Systematic review on the management of chronic constipation in North America. *American Journal of Gastroenterology, 100*(Suppl 1), S5-S21.

Burkitt, D. P., Walker, A.R.P., & Painter, N.S. (1974). Dietary fiber and disease. *Journal of the American Dietetic Association, 229*(8), 1068-1074.

Canadian Food Inspection Agency. (2003). *Guide to Food Labelling and Advertising, Chapter 6, Section 6.8.* Retrieved from the Health Canada website on November 5, 2008: http://www.inspection.gc.ca/english/fssa/labeti/guide/ch6ae.shtml.

Candy, D. C. A., & Edwards, D. (2003). The management of chronic constipation. *Current Paediatrics, 13*(2), 101-106.

Carroccio, A., Scalici, C., Marest, E., Di Prima, L., Cavataio, F., Noto, D., *et al.* (2005). Chronic constipation and food intolerance: A model of proctitis causing constipation. *Scandinavian Journal of Gastroenterology, 40*(1), 33-42.

Castiglia, P. (2001). Constipation in children. *Journal of Pediatric Health Care, 15*(4), 200-202.

Castillejo, G., Bullo, M., Anguera, A., Escribano, J., & Salas-Salvado, J. (2006). A controlled, randomized, double-blind trial to evaluate the effect of a supplement of cocoa husk that is rich in dietary fiber on colonic transit in constipated pediatric patients. *Pediatrics, 118*(3), e641-648.

Causey, J. L., Feirtag, J. M., Gallaher, D. D., Tungland, B. C., & Slavin, J. L. (2000). Effects of dietary inulin on serum lipids, blood glucose and the gastrointestinal environment in hypercholesterolemic men. *Nutrition Research, 20*(2), 191-201.

Centre for Disease Control and Prevention. *The Use and Interpretation of the CDC Growth Charts.* (n.d.). Retrieved November 6, 2008, from Centre for Disease Control and PreventionWeb site : http://www.cdc.gov/nccdphp/dnpa/growthcharts/resources/index.htm#interpretation

Chinda, D., Nakaji, S., Fukuda, S., Sakamoto, J., Shimoyama, T., Nakamura, T., *et al.* (2004). The fermentation of different dietary fibers is associated with fecal clostridia in men. *Journal of Nutrition, 134*(8), 1881-1886.

Clarke, M. C. C., Chow, C. S., Chase, J. W., Gibb, S., Hutson, J. M., & Southwell, B. R. (2008). Quality of life in children with slow transit constipation. *Journal of Pediatric Surgery, 43*(2), 320-324.

Coppa, G. V., Gabrielli, O., Pierani, P., Catassi, C., Carlucci, A., & Giogi, P. L. (1993). Changes in carbohydrate composition of human milk over 4 months of lactation. *Pediatrics, 91*(3), 637-641.

Healthy Bowel Habits for Children. (2007). Retrieved November 6, 2008, from the Canadian Paediatric Society, Caring for Kids Web site: http://www.caringforkids.cps.ca/healthybodies/healthybowel.htm

Corazziari, E., Staiano, A., Miele, E., Greco, L., & Italian Society of Pediatric Gastroenterology, Hepatology, and Nutrition. (2005). Bowel frequency and defecatory patterns in children: A prospective nationwide survey. *Clinical Gastroenterology & Hepatology, 3*(11), 1101-1106.

Corkins, M. R. (2005). Are diet and constipation related in children? *Nutrition in Clinical Practice, 20*(5), 536-539.

Coughlin, E. C. (2003). Assessment and management of pediatric constipation in primary care. *Pediatric Nursing, 29*(4), 296-301.

Daher, S., Tahan, S., Sole, D., Naspitz, C. K., Patricio, F. R. S., Fagundes-Neto, U., *et al.* (2001). Cow's milk intolerance and chronic constipation in children. *Pediatric Allergy and Immunology, 12*(6), 339-342.

Dahl, W. J., Whiting, S. J., Healey, A., Zello, G. A., & Hildebrandt, S. L. (2003). Increased stool frequency occurs when finely processed pea hull fiber is added to usual foods consumed by elderly residents in long-term care. *Journal of the American Dietetic Association, 103*(9), 1199-1202.

Davies, G. J., Crowder, M., Reid, B., & Dickerson, J. W. (1986). Bowel function measurements of individuals with different eating patterns. *Gut, 27*(2), 164-169.

de Carvalho, E. B., Vitolo, M. R., Gama, C. M., Lopez, F.A., Taddei, J. A. C., & de Morais, M. B. (2006). Fiber intake, constipation, and overweight among adolescents living in Sao Paulo city. *Nutrition, 22*(7-8), 744-749.

de Lorijn, F., van Wijk, M. P., Reitsma, J. B., van Ginkel, R., Taminiau, J. A. J. M., & Benninga, M. A. (2004). Prognosis of constipation: clinical factors and colonic transit time. *Archives of Disease in Childhood, 89*(8), 723-727.

Den Hond, E. M., Geypens, B. J., & Ghoos Y. F. (2000). Effect of high performance chicory inulin on constipation. *Nutrition Research, 20*(5), 731-736.

Devaney, B., Ziegler, P., Pac, S., Karwe, V., & Barr, S. Nutrient intakes of infants and toddlers. *Journal of the American Dietetic Association, 104*(1 Suppl 1), s14-21.

Dikeman, C. L., & Fahey, G. C. (2006). Viscosity as related to dietary fiber: a review. *Critical Reviews in Food Science Nutrition, 46*(8), 649-663.

DiPalma, J. A., & Gremse, D. A. (2001). Chronic constipation in children: Rational management. *Consultant, 41*(13), 1723-1732.

Douglas, L. (2003). Prebiotics overview: Reviewing prebiotic ingredients in terms of their health benefits, applications and place within the nutraceuticals landscape. *Nutraceuticals World, 6*(9), 80-82.

Douglas, L. C. & Sanders, M. E. (2008). Probiotics and prebiotics in dietetics practice. *Journal of the American Dietetic Association, 108*(3), 510-521.

Dubois, C., Borel, P., Cara, L., Armand, M., Senft, M., & Portugal, H. (1995). Effects of pea and soybean fibre on postprandial lipaemia and lipoproteins in healthy adults. *European Journal of Clinical Nutrition, 47*(7), 508-520.

Edwards, C. A., & Parrett, A. M. (2003). Dietary fibre in infancy and childhood. *Proceedings of the Nutrition Society, 62*(1), 17-23.

Englyst, K., N., Liu, S., & Englyst, H. N. (2007). Nutritional characterization and measurement of dietary carbohydrates. *European Journal of Clinical Nutrition, 61*(Suppl 1), 682-684.

Fontana, M., Bianchi, C., Cataldo, F., Conti Nibali, S., Cucchiara, S., Gobio Casali, L., *et al.* (1989). Bowel frequency in healthy children. *Acta Paediatrica Scandinavica, 78*(5), 682-684.

Garcia-Barcelo, M., *et al.* (2007). Application of HapMap data to the evaluation of 8 candidate genes for pediatric slow transit constipation. *Journal of Pediatric Surgery, 42*(4), 666-671.

Gibson, G. R., & Roberfroid, M. B. (1995). Dietary modulation of the human colonic microbiota: Introducing the concept of prebiotics. *Journal of Nutrition, 125*(6), 1401-1412.

Gibson, G. R., Probert, H. M., Van Loo, J., Rastall, R. A., & Roberfroid, M. B. (2004). Dietary modulation of the human colonic microbiota: Updating the concept of prebiotics. *Nutrition Research Reviews, 17*(2), 259-275.

Grant, G., Duncan, M., Alonso, R., & Marzo, F. (2003) Peas and lentils. In B. Cabalero (ed). *Encyclopedia of Food Sciences and Nutrition, 2nd edition,* (pp. 4433-4440). Amsterdam: Elsevier Science B.V.

Gray, D.S. (1995). The clinical uses of dietary fiber. *American Family Physician, 51*(2), 419-425.

Guedon, C., Ducrotte, P., Antoine, J. M., Denis, P., Colin, R., & Lerebours, E. (1996). Does chronic supplementation of the diet with dietary fibre extracted from pea or carrot affect colonic motility in man? *British Journal of Nutrition, 76*(1), 51-61.

Guimaraes, E. V., Goulart, E. M., & Penna, F. J. (2001). Dietary fiber intake, stool frequency and colonic transit time in chronic functional constipation in children. *Brazilian Journal of Medical & Biological Research, 34*(9), 1147-1153.

Gutierrez, C., Marco, A., Nogales, A., & Tebar, R. (2002). Total and segmental colonic transit time and anorectal manometry in children with a chronic idiopathic constipation. *Journal of Pediatric Gastroenterology and Nutrition, 35*(1), 31-38.

Hampl, J., Betts, N. & Benes, B. (1998). The 'age+5' rule: Comparisons of dietary fiber intake among 4- to 10-year-old children. *Journal of the American Dietetic Association, 98*(12), 1418-1423.

Hansen, I., Bach Knudsen, K. E., & Eggum, B.O. (1992). Gastrointestinal implications in the rat of wheat bran, oat bran and pea fibre. *British Journal of Nutrition, 68*(2), 451-462.

Health Canada. (2006). *Canadian Community Health Survey, Cycle 2.2, Nutrition (2004)—Nutrient Intakes from Food Provincial, Regional and National Summary Data Tables, Volume I*. Ottawa: Publications, Health Canada.

Heine, R. G. (2006). Gastroesophageal reflux disease, colic and constipation in infants with food allergy. *Current Opinion in Allergy and Clinical Immunology, 6*(3), 220-225.

Hunt, R. (1993). Therapeutic role of dietary fibre. *Canadian Family Physician, 39*, 897-900, 903-10.

Hutson, J. M., McNamara, J., Gibb, S., & Shin, Y.- M. (2001). Slow transit constipation in children. *Journal of Paediatrics and Child Health, 37*(5), 426-430.

Hyams, J., Colletti, R., Faure, C., Gabriel-Martinez, E., Maffei, H. V. L., Morais, M.B., *et al.* (2002). Functional Gastrointestinal disorders: Working group report of the

First World Congress of Pediatric Gastroenterology, Hepatology, and Nutrition. *Journal of Pediatric Gastroenterology,135*(Suppl 2), S110-S117.

Hyman, P. E., Milla, P. J., Benninga, M. A., Davidson, G. P., Fleisher, D. F., & Taminiau, J. (2006). Childhood functional gastrointestinal disorders: Neonate/toddler. *Gastroenterology, 130*(5), 1519-1526.

Iacono, G., Cavataio, F., Montalto, G., Florena, A., Tumminello, M., Soresi, M., *et al.* (1998). Intolerance of cow's milk and chronic constipation in children. *New England Journal of Medicine, 339*(16), 1100-1104.

Iacono, G., Bonventre, S., Scalici, C., Maresi, E., Di Prima, L., Soresi, M., *et al.* (2006). Food intolerance and chronic constipation: manometry and histology study. *European Journal of Gastroenterology and Hepatology, 18*(2), 143-150.

Institute of Medicine, Food and Nutrition Board. (2001). *Dietary Reference Intakes: Proposed Definition of Dietary Fiber.* Washington, DC: National Academies Press.

Institute of Medicine, Food and Nutrition Board. (2002). *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids Cholesterol, Protein, and Amino Acids (Macronutrients).* Washington, DC: National Academies Press.

Ip, K. S., Lee, W. T., Chan, J. S., & Young, B. W. (2005). A community-based study of the prevalence of constipation in young children and the role of dietary fibre. *Hong Kong Medical Journal, 11*(6), 431-436.

Jenkins, D. J., Kendall, C. W., Vuksan, V., Augustin, L., S., Li, Y., Lee, B., *et al.* (1999). The effect of wheat bran particle size on laxation and colonic fermentation. *Journal of the American College of Nutrition, 18*(4), 339.

Keshtgar, A. S., Ward, H. C., & Clayden, G. S. (2004). Diagnosis and management of children with intractable constipation. *Seminars in Pediatric Surgery, 13*(4), 300-309.

Kimm, S. Y. (1995). The role of dietary fiber in the development and treatment of childhood obesity. *Pediatrics, 96*(5 Pt 2), 1010-1014.

Kleessen, B., Hartmann, L., & Blaut, M. (2001). Oligofructose and long-chain inulin influence the gut microbial ecology of rats associated with a human faecal flora. *British Journal of Nutrition, 86*(2), 291-300.

Kranz, S., Mitchell, D. C., Siega-Riz, A. M., & Smiciklas-Wright, H. (2005). Dietary fiber intake by American preschoolers is associated with more nutrient-dense diets. *Journal of the American Dietetic Association, 105*(2), 221-225.

Kruse, H. P., Kleessen, B., & Blaut, M. (1999). Effects of inulin on faecal bifidobacteria in human subjects. *British Journal of Nutrition, 82*(5), 375-382.

Lee, W. T. K., Ip, K. S., Chan, J. S. H., Lui, N. W. M., & Young, B. W. Y. (2008). Increased prevalence of constipation in pre-school children is attributable to under-consumption of plant foods: A community-based study. *Journal of Paediatrics and Child Health, 44*(4), 170-175.

Lewis, S. J., & Heaton, K. W. (1997). Stool form scale as a useful guide to intestinal transit time. *Scandinavian Journal of Gastroenterology, 32*(9), 920-924.

Lewis, S. J., & Heaton, K. W. (1999). Roughage revisited: The effect on intestinal function of inert plastic particles of different sizes and shape. *Digestive Diseases and Sciences, 44*(4), 744-49.

Loening-Baucke, V. (1993). Chronic constipation in children. *Gastroenterology, 105*(5), 1557-1564.

Loening-Baucke, V., Miele, E., & Staiano, A. (2004). Fiber (glucomannan) is beneficial in the treatment of childhood constipation. *Pediatrics, 113*(3 Pt 1), e259-64.

Loening-Baucke, V. (2005). Prevalence, symptoms and outcome of constipation in infants and toddlers. *Journal of Pediatrics, 146*(3), 359-363.

Malkki, Y. (2001). Physical properties of dietary fiber as keys to physiological functions. *Cereal Foods World, 46*(5), 196-199.

Maffei, H. V., & de Morais, M. B. (2005). Defining constipation in childhood and adolescence: From Rome, via Boston, to Paris and...? *Journal of Pediatric Gastroenterology & Nutrition, 41*(4), 485-486.

Malkki, Y. (2001). Physical properties of dietary fiber as keys to physiological functions. *Cereal Foods World, 46*(5), 196-199.

Martlett, J. A., McBurney, M. I., Slavin, J. L., & American Dietetic Association. (2002). Position of the American Dietetic Association: Health implications of dietary fiber. *Journal of the American Dietetic Association, 102*(7), 993-1000.

McClung, H. J., Boyne, L. J., Linsheid, T., Heitlinger, L. A., Murray, R. D., & Fyda, J. *et al.* (1993). Is combination therapy for encopresis nutritionally safe? *Pediatrics, 91*(3), 591-594.

McClung, H. J., Boyne, L., & Heitlinger, L. (1995). Constipation and dietary fiber intake in children. *Pediatrics, 96*(5 Pt 2), 999-1000.

McEligot, A. J., Gilpin, E. A., Rock, C. L., Newman, V., Hollenbach, K. A., Thomson, C. A., *et al.* (2002). High dietary fiber consumption is not associated with gastrointestinal discomfort in a diet intervention trial. *Journal of the American Dietetic Association, 102*(4), 549-551.

Misra, S., Lee, A., & Gensel, K. (2006). Chronic constipation in overweight children. *Journal of Parenteral and Enteral Nutrtion, 30*(2), 81-84.

Monge-Rojas, R., & Rivas, H. N. (2001). Total dietary fiber in urban and rural Costa Rican adolescents' diets. *Archivos Latinoamericanos de Nutrición, 51*(4), 340-352.

Mongeau, R., & Brooks, S.P.J. (2003) Dietary Fibre. In B. Cabalero (ed). *Encyclopedia of Food Sciences and Nutrition, 2nd edition,* (pp. 1813-1823).Amsterdam: Elsevier Science B.V.

Morais, M. B., Vitolo, M. R., Aguirre, A. N., & Fagundes-Neto, U. (1999). Measurement of low dietary fiber intake as a risk factor for chronic constipation in children. *Journal of Pediatric Gastroenterology & Nutrition, 29*(2), 132-135.

Moshfegh, A. J., Friday, J. E., Goldman, J. P., & Chug Ahuja, J. K. (1999). Presence of inulin and oligofructose in the diets of Americans. *Journal of Nutrition, 129*(Suppl), S1407-1411.

Murch, S. (2006). Allergy and intestinal dysmotility – Evidence of genuine causal linkage? *Current Opinion in Gastroenterology, 22*(6), 664-671.

Myo-Khin, Thein-Win-Nyunt, Kyaw-Hla, S., Thein-Thein-Myint, & Bolin, T. D. (1994). A prospective study on defecation frequency, stool weight, and consistency. *Archives of Disease in Childhood, 71*(4), 311-313.

Nicklas, T. A., Farris, R. P., Myers, L., & Berenson, G. S. (1995). Dietary fiber intake of children: The Bogalusa heart study. *Pediatrics, 96*(5 Pt 2), 988-994.

NASPGHAN Constipation Guideline Committee. (2006). Evaluation and treatment of constipation in infants and children: recommendations of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition. *Journal of the Pediatric Gastroenterology and Nutrition, 43*(3), e1-13.

Nyman, M. (2002) Fermentation and bulking capacity of indigestible carbohydrates: The case of inulin and oligofructose. *British Journal of Nutrition, 87*(Suppl 2), S163-S168.

Osatakul, S., Yossuk, P., & Mo-suwan, L. (1995). Bowel habits of normal Thai children. *Journal of Pediatric Gastroenterology & Nutrition, 20*(3), 339-342.

Otten, J. J., Hellwig, J. P., & Meyers, L. D. (Eds.). (2006). *Dietary reference intakes: the essential guide to nutrient requirements* (p. 110-121). Washington, DC: National Academies Press.

Ozokutan, B. H., Zoroglu, S., Ceylan, H., & Ozkan, K. U. (2005). Psychological evaluation of children with idiopathic constipation and their parents. *Pediatrics International, 47*(3), 311-315.

Paese, P., Staiano, A., Bausano, G., Cucchiara, S., & Corazziari, E. (1985). Bowel frequency in healthy subjects. *Italian Journal of Gastroenterology, 17*(3), 133-135.

Pashankar, D. S., & Loening-Baucke, V. (2005). Increased prevalence of obesity in children with functional constipation evaluated in an academic medical center. *Pediatrics, 116*(3), e377-80.

Paulo, A. Z., Amancio, O. M. S., de Morais, M. B., & Tabacow, K. M. M. D. (2006). Low dietary fiber intake as a risk factor for recurrent abdominal pain in children. *European journal of Clinical Nutrition, 60*(7), 823-827.

Pereira, M. A., & Ludwig, D. S. (2001). Dietary fiber and body-weight regulation: Observations and mechanisms. *Pediatric Clinics of North America, 48*(4), 969-980.

Pham, T. T., & Shah, N. P. (2008). Effects of lactulose supplementation on the growth of bifidobacteria and biotransformation of isoflavone glycosides to isoflavone aglycones in soymilk. *Journal of Agricultural and Food Chemistry, 56*(12), 4703-4709.

Price, K.J., & Elliott, T.M. (2001). Stimulant laxatives for constipation and soiling in children. *Cochrane Database of Systematic Reviews, Issue 3,* Art. No.: CD002040. DOI: 10.1002/14651858.CD002040. Retrieved February 18, 2008, from http://www.cochrane.org/reviews/.

Rasquin, A., Di Lorenzo, C., Forbes, D., Guiraldes, E., Hyams, J. S., Staiano, A., *et al.* (2006). Childhood functional gastrointestinal disorders: Child/adolescent. *Gastroenterology, 130*(5), 1527-1537.

Roberfroid, M. B., Bornet, F., Bouley, C., & Cummings, J. H. (1995). Colonic microflora: Nutrition and health. *Nutrition Reviews, 53(*5), 127-30

Roberfroid, M. B. (2002). Functional foods: Concepts and application to inulin and oligofructose. *British Journal of Nutrition, 87*(suppl.2), S139-S143.

Roberfroid, M. B. (2005). Introducing inulin-type fructans. *British Journal of Nutrition, 93*(Suppl 1), S13-S25.

Roberfroid, M. B. (2007). Prebiotics: The concept revisited. *The Journal of Nutrition, 137*(3), 830S-837S.

Roma, E., Adamidis, D., Nikolara, R., Constantopoulos, A., & Messaritakis, J. (1999). Diet and chronic constipation in children: The role of fiber. *Journal of Pediatric Gastroenterology & Nutrition, 28*(2), 169-174.

Rose, D. J., DeMeo, M. T., Keshavarzian, A., & Hamaker, B. R. (2007). Influence of dietary fiber on inflammatory bowel disease and colon cancer: importance of fermentation pattern. *Nutrition Reviews, 65*(2), 51-62.

Saldanha, L. G. (1995). Fiber in the diet of US children: Results of national surveys. *Pediatrics, 96*(5 Pt 2), 994-997.

Salimen, S., & Salimen, E. (1997). Lactulose, lactic acid bacteria, intestinal microecology and mucosal protection. *Scandinavian Journal of Gastroenterology, 222*(Suppl), 45-48.

Sandstrom, B., Hansen, L. T., Sorensen, A. (1994). Pea fiber lowers fasting and postprandial blood triglyceride concentrations in humans. *Journal of Nutrition, 124*(12), 2386-2396.

Scalici, C., Licastro, G., Manzoni, D., & Sferlazza, C. (2005). Cow's milk intolerance and chronic constipation in children: A clinical and histology study. *Acta Pediatrica Mediterranea, 21*(2), 85-88.

Senn, S. (2002). *Cross-over Trials in Clinical Research* (2nd ed.). Chichester, England: Wiley.

Sherrington, C., & Forbes, D. (2005). RE: Chronic constipation in children: Organic disorders are a major cause. *Journal of Paediatrics and Child Health, 41*(11), 610-611.

Slavin, J.L. (2005). Dietary fiber and body weight. *Nutrition, 21*(3), 411-418.

Slavin, J.L. (2008). Position of the American Dietetic Association: Health implications of dietary fiber. *Journal of the American Dietetic Association, 108*(10), 1716-1731.

Southwell, B.R., King, S. K., & Hutson, J. M. (2005). Chronic constipation in children: Organic disorders are a major cause. *Journal of Paediatric Child Health, 41*(1), 1-15.

Spiller, R.C. (1994). Pharmacology of dietary fibre. *Pharmacology and Therapeutics, 62*(3), 407-27.

Taylor, C. J., & Mahenthiralingam, E. (2006). Functional foods and paediatric gastro-intestinal health and disease. *Annals of Tropical Paediatrics, 26*(2), 79-86.

Tungland, B. C., & Meyer, D. (2002). Nondigestible oligo- and polysaccharides (dietary fiber): Their physiology and role in human health and food. *Comprehensive Reviews in Food Science and Food Safety, 3*, 73-92.

Vanderhoof, J. A., Perry, D., Hanner, T. L., & Young, R. J. (2001). Allergic constipation: Association with infantile milk allergy. *Clinical Pediatrics, 40*(7), 399-402.

van Ginkel, R., Reitsma, J. B., Buller, H. A., van Wijk, M. P., Taminiau, J. A., & Benninga, M. A. (2003). Childhood constipation: Longitudinal follow-up beyond puberty. *Gastroenterology, 125*(2), 357-363.

van Loo, J., Coussement, P., de Leenheer, L., Hoebregs, H., & Smits, G. (1995). On the presence of inulin and oligofructose as natural ingredients in the Western diet. *Critical Reviews in Food Science & Nutrition, 35*(6), 525-552.

van Loo, J., Cummings, J. H., Delzenne, N., Englyst, H., Franck, A., Hopkins, M. *et al*. (1999). Functional food properties of nondigestible oligosaccharides: A consensus report from the ENDO project. *British Journal of Nutrition, 81*(2), 121-132.

Veereman-Wauters, G. (2005). Application of prebiotics in infant foods. *British Journal of Nutrition, 93*(Suppl 1), S57-S60.

Vincent, W. J. (2005). *Statistics in Kinesiology* (3rd ed.). Human Kinetics: Chicago, IL.

Vincent, R., Roberts, A., Frier, M., Perkins, A. C., MacDonald, I. A., & Spiller, R. C. (1995). Effect of bran particle size on gastric emptying and small bowel transit in humans: A scintigraphic study. *Gut, 37*(2), 216-219.

Wagener, S., Shankar, K. R., Turnock, R. R., Lamont, G. L., & Baillie, C. T. (2004). *Journal of Pediatric Surgery, 39*(2), 166-169.

Walker, A., & Walker, B. (1985). Bowel behaviour in young black and white children. *Archives of Disease in Childhood, 60*(10), 967-970.

Weaver, L., & Steiner, H. (1984). The bowel habit of young children. *Archives of Disease in Childhood, 59*(7), 649-652.

Williams, C. L. (2006). Dietary fiber in childhood. *Journal of Pediatrics, 149*(Suppl 5), S121-130.

Williams, C. L., Bollella, M., & Wynder, E. L. (1995). A new recommendation for dietary fiber in childhood. *Pediatrics, 96*(5), 985-988.

Yong, D., & Beattie, R. M. (1998). Normal bowel habit and prevalence of constipation in primary-school children. *Ambulatory Child Health, 4*, 277-282.

Youssef, N. N., & Di Lorenzo, C. (2001). Childhood constipation: Evaluation and treatment. *Journal of Clinical Gastroenterology, 33*(3), 199-205.

Youssef, N. N., Langseder, A. L., Verga, B. J., Mones, R. L., & Rosh, J. R. (2005). Chronic childhood constipation is associated with impaired quality of life: A case-controlled study. *Journal of Pediatric Gastroenterology & Nutrition, 41*(1), 56-60.

Young, R. J., Beerman, L. E., & Vanderhoof, J. A. (1998). Increasing oral fluids in chronic constipation in children. *Gastroenterology Nursing, 21*(4), 156-161.

Zhou, J.-F., Lou, J-G., Zhou, S.-L., & Wang, J.-Y. (2005). Potential oxidative stress in children with chronic constipation. *World Journal of Gastroenterology, 11*(3), 368-371.

APPENDIX 1

Ethics Approval

3.1 Confirmation of Ethical Approval

UNIVERSITY OF SASKATCHEWAN — Biomedical Research Ethics Board (Bio-REB)

Certificate of Approval

PRINCIPAL INVESTIGATOR	DEPARTMENT	Bio #
Wendy J. Dahl	Pharmacy	07-38

INSTITUTION(S) WHERE RESEARCH WILL BE CARRIED OUT
University of Saskatchewan
Saskatoon SK

STUDENT RESEARCHERS
Carla Moreau

SPONSORING AGENCIES
SASKATCHEWAN PULSE GROWERS

TITLE: The Effect of Fibre Fortification on Stool Frequency in Children with a History of Constipation

APPROVAL DATE	EXPIRY DATE	APPROVAL OF
19-Mar-2007	18-Mar-2007	Researcher's Summary (08-May-2007) Participant Information and Consent Form (08-May-2007) Participant Information and Assent Form (19-Apr-2007) Pre-Study Questionnaire Newspaper Recruitment Advertisement Acknowledge: Physician Information Letter

Full Board Meeting X — Date of Full Board Meeting: 19-Mar-2007

Delegated Review ☐

CERTIFICATION
The study is acceptable on scientific and ethical grounds. The principal investigator has the responsibility for any other administrative or regulatory approvals that may pertain to this research study, and for ensuring that the authorized research is carried out according to governing law. This approval is valid for the specified period provided there is no change to the approved protocol or consent process.

FIRST TIME REVIEW AND CONTINUING APPROVAL
The University of Saskatchewan Biomedical Research Ethics Board reviews above minimal studies at a full-board (face-to-face) meeting. Any research classified as minimal risk is reviewed through the delegated (subcommittee) review process. The initial Certificate of Approval includes the approval period the REB has assigned to a study. The Status Report form must be submitted within one month prior to the assigned expiry date. The researcher shall indicate to the REB any specific requirements of the sponsoring organizations (e.g. requirement for full-board review and approval) for the continuing review process deemed necessary for that project. For more information visit http://www.usask.ca/research/ethics_review/.

REB ATTESTATION
In respect to clinical trials, the University of Saskatchewan Research Ethics Board complies with the membership requirements for Research Ethics Boards defined in Division 5 of the Food and Drug Regulations and carries out its functions in a manner consistent with Good Clinical Practices. This approval and the views of this REB have been documented in writing.

Michel Desautels, Ph.D., Chair
University of Saskatchewan
Biomedical Research Ethics Board

May 17, 2007
Signature Date

Please send all correspondence to:
Ethics Office
University of Saskatchewan
Room 305 Kirk Hall, 117 Science Place
Saskatoon SK S7N 5C8
Telephone: (306) 966-4053 Fax: (306) 966-2069

3.2 Status Report Form

UNIVERSITY OF SASKATCHEWAN

Biomedical Research Ethics Board (Bio-REB)
Ethics Office (VP Research, University of Saskatchewan
Room [illegible]
Saskatoon, SK [illegible]

RECEIVED
FEB 25 2008
University of Saskatchewan
Research Ethics Board (REB)

STATUS REPORT FORM

This form is submitted for the following purpose

X Annual status report and re-approval request. When was the ethics approval for this study due to expire? Date: March 18, 2008

____ Notice of study closure.

Report Prepared by: Carla Flogan Date: Feb. 14, 2008

ONGOING REVIEW REQUIREMENTS: This approval is valid for up to one year. The REB will require the submission of an annual status report at least one month prior to the expiration date indicated below. Please note if the Status Report Form is not submitted by the one-year expiry date, the ethics certificate will automatically expire.

1. **PRINCIPAL INVESTIGATOR**
   Cindy Dan!
   NOTE: An investigator who does not maintain a physical presence at the trial site in proportion to the inherent level of risk that subjects will be exposed to cannot continue to be identified as the principal investigator. The responsibility must be transferred to a new principal investigator.

2. **DEPARTMENT/DIVISION**: Nutrition Division
3. **REB FILE #**: 07-38
4. **STUDY SITE(S)**: U of Saskatchewan, Saskatoon, SK
5. **TITLE OF PROTOCOL AND PROTOCOL # (where applicable)**: The Effect of Fibre Fortification on Stool Frequency in Children with Constipation
6. **SPONSOR (where applicable)**: Saskatchewan Pulses
7. **BRIEF SUMMARY OF PROGRESS OF STUDY** (projected completion date for recruitment and data collection, number of subjects admitted to date, target enrollment, anticipated end-date). Are subjects currently receiving study treatment or interventions, or is the study only active for follow-up to endpoints?
   May 2008 - study end-date; 14 subjects enrolled to date, target enrollment - 15-20 subjects. Subjects are currently receiving the treatment
8. **ARE THERE ANY ASPECTS OF THIS STUDY WHICH SHOULD BE BROUGHT TO THE ATTENTION OF THE REB** (i.e., any new information or knowledge bearing on the anticipated risks or anticipated benefits, and therefore possibly affecting subjects' ongoing decision to participate in this study. Clinical trialists should reflect upon adverse events associated with their protocol).
   n/a
9. **WHAT ARE YOUR CURRENT SAFETY REVIEW PROCEDURES FOR THIS RESEARCH PROJECT** (i.e., drug safety monitoring board (DSMB), clinical end-point committee (CEC), hotline, periodic reporting to the ethics board)?
   n/a
10. **PRINCIPAL INVESTIGATOR**
    Signature [signature] Date: 02-18-08

For Administrative Use Only:

Approved On: Feb 29, 2008 Expiry Date: 17-Mar-2009

Signature of Chair or designate: [signature]

Please note that this form, once signed by the chair or designate, serves as your official re-approval certificate.

January 2006

APPENDIX 2

Consent Forms

2.1 Parent/Legal Guardian Information and Consent Form

Participant Information and Consent Form

Study Title: The Effect of Fibre Fortification on Stool Frequency in Children with a History of Constipation

Principal Investigator: Dr. Wendy J. Dahl is investigating the effect of fibre fortification on bowel habits of children who have experienced constipation.

Wendy Dahl RD PhD, Adjunct Professor
College of Pharmacy and Nutrition, University of Saskatchewan
110 Science Place, Saskatoon, SK, S7N 5C9

Sub-investigator: Carla Flogan RD, Graduate Student, College of Pharmacy and Nutrition, University of Saskatchewan

Study Sponsor: Saskatchewan Pulse Growers
The sponsor of this study, Saskatchewan Pulse Growers, will reimburse Dr. Wendy Dahl for the costs of undertaking this study by providing a graduate student stipend to Carla Flogan. However, neither the institution nor any of the investigators or staff will receive any direct financial benefit from conducting this study.

Your child is being asked to take part in this research because he/she has had constipation in the last 12 months. Participation is voluntary and you have the right to refuse your child's participation in this study. If you decide your child can volunteer, you can also withdraw him/her from the study at any time. If you do not wish your child to participate, you do not have to provide any reason for your decision, nor will your child lose the benefit of any care to which he/she is entitled or is presently receiving. Please take the time to read the following information carefully and to discuss it with your family, friends, and doctor before you decide.

Please note that children with Type 1 or Type 2 diabetes or food allergies are excluded from this study. Inform the researchers if your child has either of these conditions.

Purpose of the Study:

The purpose of this study is to determine whether adding fibre to usual foods improves the intake of dietary fibre, as well as increasing the number of bowel movements. Some children do not consume enough dietary fibre. In many cases, a diet high in dietary fibre has been shown to increase the number of bowel movements a child has.

Benefits:

There may not be any direct benefits to your child for participating in this study. Your child's constipation may or may not improve during the study period. Knowledge gained from this study may help to improve nutritional care for children who experience chronic constipation.

Procedures:

1. Your child will be asked to participate in this study for a period of six weeks. This will be made up of two consecutive periods of three weeks. Your child will be asked to eat the food provided as part of his/her snacks. During one half of the study, the food will contain added fibre and during the other half of the study, there will be no fibre added to the food. You will also add a small package of white powder containing fibre or a starch (no fibre) to food or beverages that your child consumes. Neither you nor the researchers will know when your child is consuming the food or powder with fibre. This will be achieved by randomly assigning your child to start with either the fibre added or no fibre added arm of the study.

2. You will need to meet with the pediatric dietitian (Carla Flogan) to go over the study information. At that time, you will be asked to fill out a short questionnaire about your child's history of constipation and any related medical diagnoses. You will also be asked to list any medications or supplements that your child takes. There will be three visits with the pediatric dietitian at the start of the study, at the mid-point (after three weeks) and at the end of the study (after six weeks).

3. You will be asked to fill out a three day food record for your child during each three-week period of the study (a total of six days of food records) for your child. This will need to be two non-consecutive weekdays and one weekend day for each study period.

4. Your child will be requested to fill out a daily record of his/her stool habits including appearance, frequency and consistency. If your child is unable to fill out the study diary, you would be requested to do this on his/her behalf.

5. You will be asked to fill out a short questionnaire at the mid-point (at three weeks) and end of the study period (after six weeks).

6. Your child will be able to consume his/her regular diet. However, your child will need to replace two snack foods every day with foods that will be provided to you by the researchers. These foods may or may not contain added fibre. The food can be picked up when you meet with the study dietitian. The powder fibre or starch can be added to foods or beverages that your child already consumes. Any unused portions will be returned to the researchers at the end of each study period, again at the visits with the study dietitian.

- The white powder packages will contain either inulin (a food fibre) or maltodextrin (a food starch). The inulin or maltodextrin will be similar in appearance and will contribute very little to the flavour of the food/beverages that they are added to.
- Your child will be asked to eat two snacks every day such as crackers, cookies, snack cakes and granola bars instead of his/her regular snacks or desserts. During half of the study, they will have pea fibre added to them. During the other half, they will not have added fibre in them. Your child will not know when he/she is eating a regular food or a food with added fibre.
- Please note that some of the snacks contain nuts or have come into contact with nuts. This should be kept in mind if your child's school is nut-free, as they should not be sent to school.

It is not expected that changing your child's snacks will require any additional time. Your time commitment for this study is estimated at about 10 hours over the course of the study. This includes three interviews of one hour each at the University of Saskatchewan at the start, mid-point and end of the study, the time it takes to help your child with daily stool records and the two three-day food records that you will do for your child.

Confidentiality:

While absolute confidentiality cannot be guaranteed, every effort will be made to ensure that the information you provide for this study is kept entirely confidential. Your child's name will not be attached to any information. It will not be mentioned in any study report, nor be made available to anyone except the research team. The research team may wish to present the results of this study in scientific journals or at conferences and workshops, but your identity will not be revealed.

With your permission, we will inform your child's family physician of your participation in this study. This is to help ensure that there is no medical reason, to the best of your family physician's knowledge, your child should not participate in this study.

Participation is Voluntary:

Your child's participation in this study is entirely voluntary. You have the right to refuse to allow your child to participate and you can withdraw your child from the study at any time, for any reason. Early withdrawal from the study will not result in any sort of penalty.

Alternative Treatment:

Your child does not have to participate in this study to receive treatment for his/her constipation. Your family physician or pediatrician can recommend other treatment options, such as medications or behavioural approaches.

Potential Risks:

The risk of consuming fibre-fortified food may include symptoms such as gas and bloating.

Research Related Injury:

There will be no costs to you for your participation in this study. You will not be charged for any research procedures and participating in this study will not affect your care. In the event that your child becomes ill or injured as a result of participating in this study, medical treatment will be made available at no additional cost to you.

Compensation:

You will be provided with $45 for your participation in this research study. This compensation is intended to cover the costs of parking, travel and your time.

Contacts:

If you have any questions with regards to this research project, please do not hesitate to contact the researchers below:

Carla Flogan (Moreau)	(306) 933-4535
Wendy Dahl	(306) 655-1310

This study has been approved, on ethical grounds, by the Biomedical Research Ethics Board (Bio-REB) of the University of Saskatchewan. If you have any questions about your rights as a research subject, you may contact the chair of the Biomedical Ethics Board, c/o the Ethics Office, University of Saskatchewan at (306) 966 4053.

The contents of this consent form have been explained to me. I have been able to ask questions about the study and these questions have been answered to my satisfaction. I

have received a copy of the consent form for my own records. I freely consent to my child's participation in this study. I am not waiving any of my legal rights by signing this consent form.

I consent to a letter being sent to my family physician about my child's participation in this study.
□ Yes □ No

SIGNATURES

Parent/Legal Guardian: _____Date: _____

Research Coordinator: _____ Date: _____

2.2 Participant Information and Assent Form

Participant Information and Assent Form

Study title: The Effect of Fibre Fortification on Stool Frequency in Children with a History of Constipation

You are invited to be a volunteer in this study because you have had constipation in the past year.

Taking part in this study is not part of your schoolwork. This study is not part of your medical treatment. You do not have to take part in this study. If you decide to take part, you can quit at any time for any reason. Quitting the study will not result in any penalty or loss of health care services.

If you volunteer for this study,

- You will be asked to add a white powder food fibre or food starch to the foods/drinks you eat. During one part of the study, it will have inulin (a food fibre) in it. A food fibre is the part of plant foods that we can't break down in our bodies. During the other half of the study, it will have a food starch in it. Food starch is in pasta, bread and rice. You will not know if you are eating a food starch or food fibre.
- You will be asked to eat two snacks every day such as crackers, cookies, snack cakes and granola bars instead of your regular snacks or desserts. During half of the study, these foods will have the outsides of peas hidden in them. During the other half, they will not have added pea fibre in them. You will not know when you are eating a regular food or a food with added fibre.
- You will be asked to write down the snacks you eat, how your tummy feels and to describe things about going to the bathroom in a study diary every day. You can write this down at the end of each day and you don't have to take your study diary to school. This will take about 5 minutes to do each day.

After eating food with added fibre, you may notice changes when you go to the bathroom. You may notice more or less gas and bloating. You may notice changes in your stools. You may notice changes in how often you need to pass stools.

Being part of this study will be kept private. No one other than the research people will know that you are taking part in this study. No one at your school will be told about the study. What you tell the dietitian will also be kept private. She will not use your name to tell the other researchers about how you are feeling.

The snacks with pea fibre will be in packaging that might look different than other food such as plastic bags. The white powder might look like medicine instead of food. These

snacks might have different packaging than the food and drinks other kids take to school.

The information we find out from this study will be used to write a report for a medical or nutrition journal. Your name will not be used.

If you have any questions about this research project, please call:

Carla Flogan (Moreau)	(306) 933-4535
Wendy Dahl	(306) 655-1310

The information on this form has been explained to me. I have been able to ask questions about the study and these questions have been answered in a way that I understand. I have a copy of this form for my own records.

SIGNATURES

Study Volunteer: _____ Date: _____

Research Coordinator: _____ Date: _____

Witness: _____ Date: _____

APPENDIX 3

Recruitment

3.1 Newspaper Recruitment Advertisement

Research Subjects Needed

A study is being conducted at the University of Saskatchewan to see if adding fibre to snack foods will help relieve constipation in children.

We are looking for children who:

- ✓ Are 2-10 years old
- ✓ Have had a history of constipation in the last 12 months

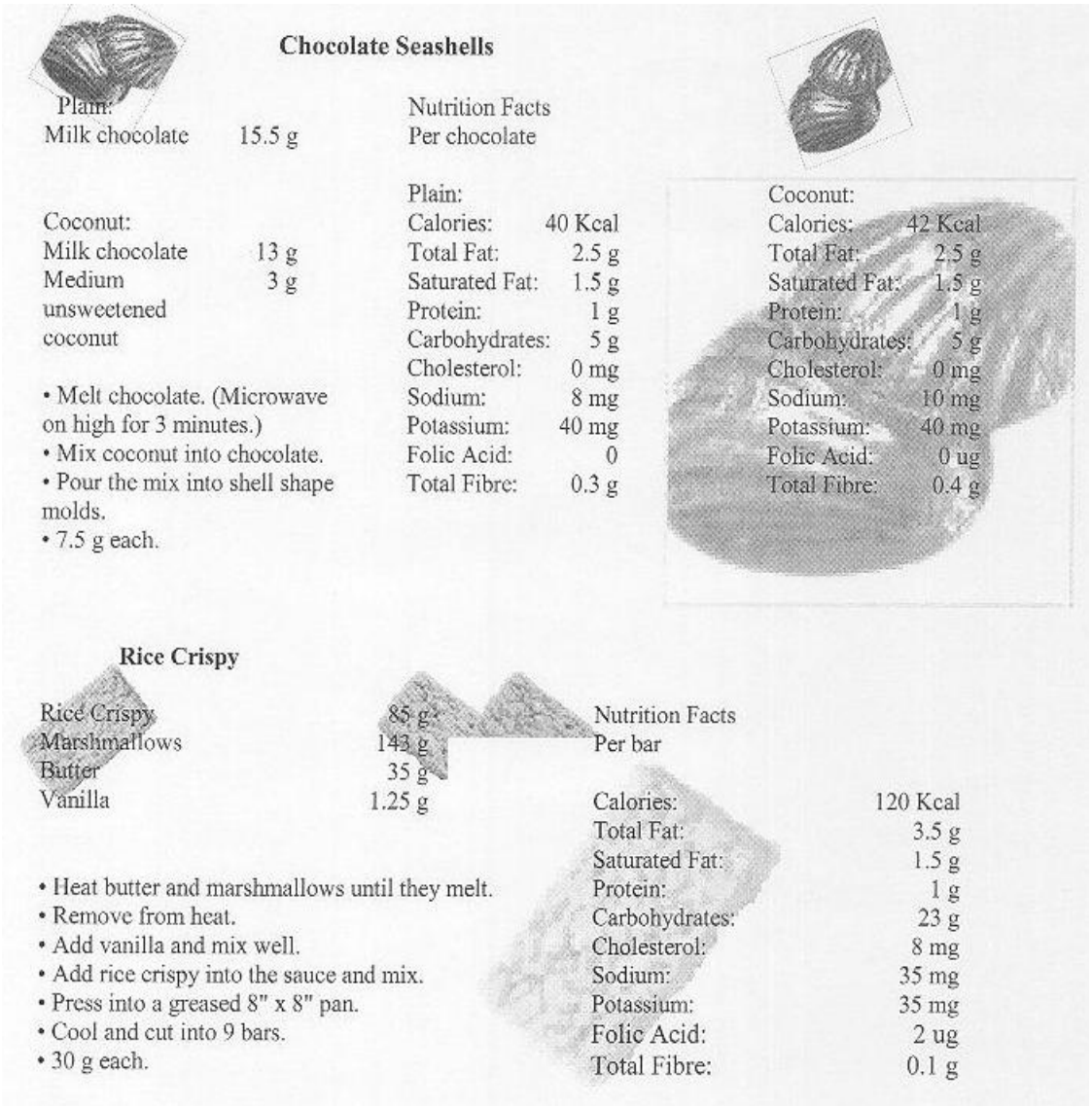
The time commitment includes 3 visits to the University of Saskatchewan over a period of about six weeks. Compensation is provided. For more information, interested parents can contact Carla, Nutrition Graduate Student, College of Pharmacy and Nutrition at 260-5546 or carla.flogan@usask.ca. Please leave your contact information and you will receive a response within 1-2 days. The principal investigator for this study is Dr. Wendy Dahl, College of Pharmacy and Nutrition.

3.2 Recruitment Poster for Daycare Centres

APPENDIX 4

Study Recipes

4.1 Placebo Recipes



Chocolate Seashells

Plain:

Milk chocolate	15.5 g

Coconut:

Milk chocolate	13 g
Medium unsweetened coconut	3 g

- Melt chocolate. (Microwave on high for 3 minutes.)
- Mix coconut into chocolate.
- Pour the mix into shell shape molds.
- 7.5 g each.

Nutrition Facts
Per chocolate

Plain:	
Calories:	40 Kcal
Total Fat:	2.5 g
Saturated Fat:	1.5 g
Protein:	1 g
Carbohydrates:	5 g
Cholesterol:	0 mg
Sodium:	8 mg
Potassium:	40 mg
Folic Acid:	0
Total Fibre:	0.3 g

Coconut:	
Calories:	42 Kcal
Total Fat:	2.5 g
Saturated Fat:	1.5 g
Protein:	1 g
Carbohydrates:	5 g
Cholesterol:	0 mg
Sodium:	10 mg
Potassium:	40 mg
Folic Acid:	0 ug
Total Fibre:	0.4 g

Rice Crispy

Rice Crispy	85 g
Marshmallows	143 g
Butter	35 g
Vanilla	1.25 g

- Heat butter and marshmallows until they melt.
- Remove from heat.
- Add vanilla and mix well.
- Add rice crispy into the sauce and mix.
- Press into a greased 8" x 8" pan.
- Cool and cut into 9 bars.
- 30 g each.

Nutrition Facts
Per bar

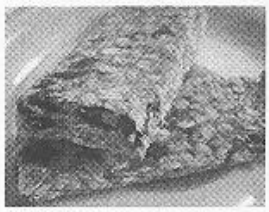
Calories:	120 Kcal
Total Fat:	3.5 g
Saturated Fat:	1.5 g
Protein:	1 g
Carbohydrates:	23 g
Cholesterol:	8 mg
Sodium:	35 mg
Potassium:	35 mg
Folic Acid:	2 ug
Total Fibre:	0.1 g

Puffed Wheat Cake

Butter	75 g
White corn syrup	170 g
Brown sugar	170 g
Vanilla	5 g
Puffed wheat	90 g
Cocoa	15 g

- Measure puffed wheat.
- Melt butter and add syrup, sugar and cocoa mixture in saucepan.
- Boil to hard ball stage. Let stand for 1 min.
- Remove from heat. Add puffed wheat and mix well.
- Press into a greased 13" x 9" pan.
- Cool and cut into 20 bars.

Nutrition Facts Per bar (28 g)	
Calories:	100 Kcal
Total Fat:	3 g
Saturated Fat:	1.5 g
Protein:	1 g
Carbohydrates:	21 g
Cholesterol:	8 mg
Sodium:	35 mg
Potassium:	60 mg
Folic Acid:	12 ug
Total Fibre:	0.7 g



No-Bake Granola Bars

Crispy rice cereal	35 g
Oatmeal, quick cooking	100 g
Raisins	35 g
Chocolate chips	45 g
Brown sugar	40 g
Light corn syrup	80 g
Peanut butter	65 g
Vanilla	2.5 g

- Shake cereal, oatmeal, raisins, and chocolate chips in a plastic bag.
- Combine brown sugar and syrup.
- Stirring constantly, bring to a boil then remove from heat.
- Stir in peanut butter and vanilla.
- Add cereal mixture and mix well.
- Press into ungreased 8" x 8" pan.
- Cool and cut into 16 bars.
- 25 g per bar.

Nutrition Facts
Per bar

Calories:	110 g
Total Fat:	33 g
Saturated Fat:	11 g
Protein:	23 g
Carbohydrates:	19 g
Cholesterol:	0 mg
Sodium:	70 mg
Potassium:	90 mg
Folic Acid:	32 ug
Total Fibre:	1.0 g

Raisin Honey Chews

Butter	85 g
Sugar	75 g
Honey	80 g
Egg	25 g
Milk (water)	44 g
Flour	100 g
Baking soda	2.5 g
Salt	1.5 g
Oatmeal, quick cooking	100 g
Seedless raisins	65 g

- Melt butter (microwave on high for 1 min.) and add sugar, honey and egg; mix well.
- Add milk (water).
- Stir in flour, soda, and salt; beat well.
- Add oatmeal and raisins.
- Put it in fridge for about 20 min.
- Shape the dough into 15 g balls and squish them. (Makes about 38 cookies)
- Put them onto greased baking sheets.
- Bake above oven centre at 375° for 10 min.
- Let stand on pans 3 min, then remove to wire racks to cool.

Nutrition Facts:
Per two cookies

Calories:	110 kcal
Total Fat:	4 g
Saturated Fat:	2 g
Protein:	2 g
Carbohydrates:	20 g
Cholesterol:	15 mg
Sodium:	110 mg
Potassium:	70 mg
Folic Acid:	40 µg
Total Fibre:	0.4 g

Granola Bars

Butter	35 g
Marshmallows	143 g
Vanilla Extract	2.5 g
Granola cereal (Mueslix Flakes)	100 g
Quick Cooking Oatmeal	100 g
Cranberry raisins, diced	22 g

- Heat butter and marshmallows until they melt.
- Remove from heat.
- Add vanilla and mix well.
- Add cereal and cranberry raisins into the sauce and mix them evenly.
- Press into a greased 8" x 8" pan.
- Cool and cut into 10 bars.

Nutrition Facts
Per bar

Calories:	164.8 kcal
Total Fat:	5.9 g
Protein:	3.4 g
Carbohydrates:	27 g
Cholesterol:	7.5 mg
Sodium:	62.7 mg
Potassium:	102.1 mg
Folic Acid:	55 ug
Total Fibre:	1.8 g

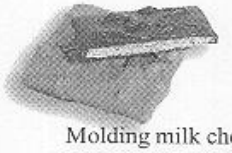
Chocolate Chip Cookies

Butter (room temperature)	113 g
White Sugar	75 g
Brown Sugar	80 g
Egg	50 g
Vanilla Extract	4.2 g
Flour	142 g
Baking Soda	2.3 g
Salt	0.7 g
Chocolate Chips	135 g

- Preheat oven to 350° F (177° C) with rack above center of oven.
- Line two baking sheets with parchment paper. Set aside.
- Cream the butter.
- Add the white and brown sugars and beat until fluffy.
- Beat in egg.
- Add the vanilla and beat until incorporated.
- In a separate bowl, combine flour, baking soda, and salt.
- Add the dry ingredients to the egg mixture and beat until incorporated.
- Add the chocolate chips half way through mixing.
- Shape the dough into 15 g balls and squish them. Put them onto baking sheets (15 cookies / sheet).
- Makes about 44 cookies.
- Bake for 10 – 12 minutes or until golden brown around the edges.
- Cool on a wire rack.

Nutrition Facts
Per two cookies

Calories:	120 kcal
Total Fat:	6 g
Saturated Fat:	3.5 g
Protein:	1 g
Carbohydrates:	18 g
Cholesterol:	20 mg
Sodium:	80 mg
Potassium:	60 mg
Folic Acid:	11 ug
Total Fibre:	0.3 g



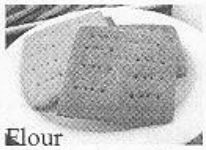
Chocolate Coated Crackers

Molding milk chocolate	11 g
Butterscotch chips	5 g
Multigrain Cracker	2 crackers

- Place butterscotch chips and chocolate in a jar.
- Microwave for 1 min 30 sec on high.
- Mix and let sit for 1 min.
- Microwave for another 1 min. 45 sec on high.
- Coat crackers with mixture.

Nutrition Facts:
Per two crackers

Calories:	120 kcal
Total Fat:	6.5 g
Saturated Fat:	3.5 g
Protein:	1 g
Carbohydrates:	15 g
Cholesterol:	3 mg
Sodium:	70 mg
Potassium:	65 mg
Folic Acid:	9 ug
Fibre:	1.3 g



Honey graham crackers

Flour	100 g
Whole wheat flour	78 g
Salt	1.5 g
Baking soda	1.5 g
Cinnamon	0.8 g
Butter	85 g
Granulated sugar	35 g
Brown sugar	15 g
Honey, creamed	15 g
Vanilla	1.25 g
Egg	25 g
Milk	45 g

• Mix the dry ingredients together in a bowl.
• With the paddle attachment of your electric mixer, beat the cold butter until it is soft.
• Add the sugars and continue beating.
• Then add the honey, vanilla, egg and milk and beat until combined.
• Add the dry ingredients to the mixer bowl and beat until a fairly firm dough is made.
• Wrap the dough in plastic and place it in the refrigerator to chill.
When the dough is firm enough to roll, lightly dust a countertop and a rolling pin and roll the dough to a scant ¼-inch thick.

• Preheat the oven to 350° F.
• Cut it into 3 cm x 6 cm and place them on a well-greased baking sheet with a margin of space to allow for spreading.
• Use a folk to pierce the crackers.
• Bake them at 350° F for 10 min. When ready, remove them to a wire rack to cool.
• 2 crackers per serving.
• Makes 25 crackers.

Nutrition Facts Per two crackers	
Calories:	120 kcal
Total Fat:	6 g
Saturated Fat:	3 g
Protein:	2 g
Carbohydrates:	17 g
Cholesterol:	25 mg
Sodium:	125 mg
Potassium:	55 mg
Folic Acid:	30 µg
Fibre:	0.6 g

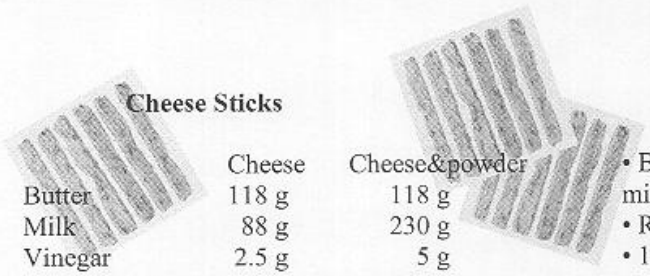
Chocolate Cheerios

Cheerios	14 g
Molding milk chocolate	10 g
Icing Sugar	3 g

• Place chocolate in jar.
• Microwave for 3 min on high.
• Coat Cheerios with the chocolate.
• Chill and dust with icing sugar.
• Makes one serving.

Nutrition Facts For one serving	
Calories:	120 kcal
Total Fat:	4 g
Saturated Fat:	2 g
Protein:	2.5 g
Carbohydrates:	21 g
Cholesterol:	2.5 mg
Sodium:	140 mg
Potassium:	100 mg
Folic Acid:	155 ug
Fibre:	1.7 g

Cheese Sticks



	Cheese	Cheese&powder
Butter	118 g	118 g
Milk	88 g	230 g
Vinegar	2.5 g	5 g
Baking soda	2.25 g	2.25 g
Salt	1.65 g	1.65 g
Flour	248 g	248 g
Water	105 g	-
Cheese (shredded)	108 g	108 g
Kraft powder	-	15 g

- Measure flour into bowl.
- Work the butter into the flour with a pastry cutter. (Add shredded cheese.)
- Stir vinegar, baking soda and salt into milk.
- Let rest for 2 min. (Stir Kraft powder into milk.)
- Add this to the butter- flour mixture.
- Form dough, roll out and make strings using a pasta machine (thinness 4).
- Bake them for 7 min. at 375° F, then fan for min at 175° F.
- Remove them to a wire rack to cool.
- 15 g for 1 serving.

Nutrition Facts
Per 15 gram serving

Calories:	80 kcal
Total Fat:	5 g
Saturated Fat:	2.5 g
Protein:	2 g
Carbohydrates:	9 g
Cholesterol:	13 mg
Sodium:	105 mg
Potassium:	40 mg
Folic Acid:	25 ug
Fibre:	2.4 g

Rice Crispy – Cranberry & Coconut

Rice crispy	40 g
Oatmeal, quick cooking	70 g
Cranberry raisins	15 g
Coconut, sweetened long	5 g
Butter	62 g
White sugar	82 g
White corn syrup	34 g
Honey	15 g
Vanilla	2.5 g

- Shake rice crispy, oatmeal, cranberry, raisins, and coconut in a plastic bag.
- Combine butter, sugar, syrup and honey in saucepan and cook at 230° F.
- Remove from heat.
- Add vanilla.
- Pour over cereal mixture; mix well.
- Press into greased 8" x 8" pan.
- Cool and cut into 10 bars.
- 1 bar for 1 serving.

Nutrition Facts
Per bar

Calories:	140 kcal
Total Fat:	6 g
Saturated Fat:	3 g
Protein:	2 g
Carbohydrates:	24 g
Cholesterol:	13 mg
Sodium:	95 mg
Potassium:	45 mg
Folic Acid:	35 ug
Fibre:	0.8 g

4.2 Recipes with Pea Fibre

Chocolate Seashells

Plain:

Milk chocolate	15.5 g
Pea hull fibre	2 g

Coconut:

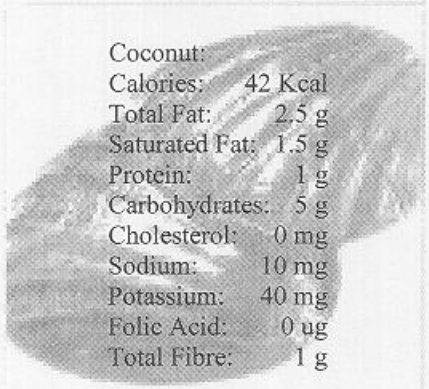
Milk chocolate	13 g
Pea hull fibre	2 g
Medium unsweetened coconut	3 g

- Melt chocolate. (Microwave on high for 3 minutes.)
- Mix fibre with chocolate and coconut.
- Pour the mix into shell shape molds.
- 7.5 g each.

Nutrition Facts
Per chocolate

Plain:

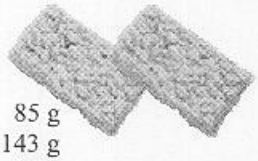
Calories:	40 Kcal
Total Fat:	2.5 g
Saturated Fat:	1.5 g
Protein:	1 g
Carbohydrates:	5 g
Cholesterol:	0 mg
Sodium:	8 mg
Potassium:	40 mg
Folic Acid:	0
Total Fibre:	1 g



Coconut:

Calories:	42 Kcal
Total Fat:	2.5 g
Saturated Fat:	1.5 g
Protein:	1 g
Carbohydrates:	5 g
Cholesterol:	0 mg
Sodium:	10 mg
Potassium:	40 mg
Folic Acid:	0 ug
Total Fibre:	1 g

Rice Crispy



Rice Crispy	85 g
Marshmallows	143 g
Butter	35 g
Vanilla	1.25 g
Pea hull fibre	18 g

- Heat butter and marshmallows in saucepan until they melt.
- Remove from heat.
- Add vanilla and fibre and mix well.
- Add rice crispy into the sauce and mix.
- Press into a greased 8" x 8" pan.
- Cool and cut into 9 bars.
- 30 g each.

Nutrition Facts
Per bar

Calories:	120 Kcal
Total Fat:	3.5 g
Saturated Fat:	1.5 g
Protein:	1 g
Carbohydrates:	23 g
Cholesterol:	8 mg
Sodium:	35 mg
Potassium:	35 mg
Folic Acid:	2 ug
Total Fibre:	2.5 g

Puffed Wheat Cake

Butter	75 g
White corn syrup	170 g
Brown sugar	170 g
Pea hull fibre	40 g
Vanilla	5 g
Puffed wheat	90 g
Cocoa	15 g

- Shake puffed wheat and fibre (20 g) in a plastic bag.
- Mix cocoa and fibre (20 g) well.
- Melt butter and add syrup, sugar and cocoa / fibre mixture.
- Boil to hard ball stage. Keep it for 1 min.
- Remove from heat. Add puffed wheat and mix well.
- Press into a greased 13" x 9" pan.
- Cool and cut into 20 bars.
- 28 g each.

Nutrition Facts Per bar	
Calories:	100 Kcal
Total Fat:	3 g
Saturated Fat:	1.5 g
Protein:	1 g
Carbohydrates:	21 g
Cholesterol:	8 mg
Sodium:	35 mg
Potassium:	60 mg
Folic Acid:	12 ug
Total Fibre:	2.2 g

No-Bake Granola Bars

Crispy rice cereal	35 g
Oatmeal, quick cooking	100 g
Raisins	35 g
Chocolate chips	45 g
Pea hull fibre	17 g
Brown sugar	40 g
Light corn syrup	80 g
Peanut butter	65 g
Vanilla	2.5 g

- Shake cereal, oatmeal, raisins, chocolate chips and 9 grams of fibre in a plastic bag.
- Combine brown sugar and syrup.
- Stirring constantly, bring to a boil then remove from heat.
- Stir in peanut butter, vanilla and 8 grams of fibre.
- Add cereal mixture and mix well.
- Press into ungreased 8" x 8" pan.
- Cool and cut into 16 bars.
- 25 g per bar.

Nutrition Facts
Per bar

Calories:	110 g
Total Fat:	33 g
Saturated Fat:	11 g
Protein:	23 g
Carbohydrates:	19 g
Cholesterol:	0 mg
Sodium:	70 mg
Potassium:	90 mg
Folic Acid:	32 ug
Total Fibre:	2.0 g

Raisin Honey Chews

Butter	85 g
Sugar	75 g
Honey	80 g
Egg	25 g
Milk (water)	44 g
Flour	100 g
Baking soda	2.5 g
Salt	1.5 g
Pea hull fibre	38 g
Oatmeal, quick cooking	100 g
Seedless raisins	65 g

• Melt butter (microwave on high for 1 min.) and add sugar, honey and egg; mix well.
• Add milk (water).
• Stir in flour, soda, salt and fibre; beat well.
• Add oatmeal and raisins.
• Put it in fridge for about 20 min.
• Shape the dough into 15 g balls and squish them. (Makes about 38 cookies)
• Put them onto greased baking sheets.
• Bake above oven centre at 375° for 10 min.
• Let stand on pans 3 min, then remove to wire racks to cool.

Nutrition Facts:
Per two cookies

Calories:	110 kcal
Total Fat:	4 g
Saturated Fat:	2 g
Protein:	2 g
Carbohydrates:	20 g
Cholesterol:	15 mg
Sodium:	110 mg
Potassium:	70 mg
Folic Acid:	40 µg
Total Fibre:	2.7 g

Granola Bars

Butter	35 g
Marshmallows	143 g
Pea hull fibre	20 g
Vanilla Extract	2.5 g
Granola cereal (Mueslic Flakes)	100 g
Quick Cooking Oatmeal	100 g
Cranberry raisins, diced	22 g

• Heat butter and marshmallows until they melt.
• Remove from heat.
• Add vanilla and fibre and mix well.
• Add cereal and cranberry raisins into the sauce and mix them evenly.
• Press into a greased 8" x 8" pan.
• Cool and cut into 10 bars.

Nutrition Facts
Per bar

Calories:	164.8 kcal
Total Fat:	5.9 g
Protein:	3.4 g
Carbohydrates:	27 g
Cholesterol:	7.5 mg
Sodium:	62.7 mg
Potassium:	102.1 mg
Folic Acid:	55 ug
Total Fibre:	3.9 g

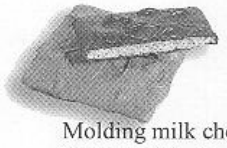
Chocolate Chip Cookies

Butter (room temperature)	113 g
White Sugar	75 g
Brown Sugar	80 g
Egg	50 g
Vanilla Extract	4.2 g
Flour	142 g
Baking Soda	2.3 g
Salt	0.7 g
Pea hull fibre	44 g
Chocolate Chips	135 g

- Preheat oven to 350° F (177° C) with rack above center of oven.
- Line two baking sheets with parchment paper. Set aside.
- Cream the butter.
- Add the white and brown sugars and beat until fluffy.
- Beat in egg.
- Add the vanilla and beat until incorporated.
- In a separate bowl, combine flour, baking soda, salt and pea hull fibre.
- Add the dry ingredients to the egg mixture and beat until incorporated.
- Add the chocolate chips half way through mixing.
- Shape the dough into 15 g balls and squish them. Put them onto baking sheets (15 cookies / sheet).
- Makes about 44 cookies.
- Bake for 10 – 12 minutes or until golden brown around the edges.
- Cool on a wire rack.

Nutrition Facts
Per two cookies

Calories:	120 kcal
Total Fat:	6 g
Saturated Fat:	3.5 g
Protein:	1 g
Carbohydrates:	18 g
Cholesterol:	20 mg
Sodium:	80 mg
Potassium:	60 mg
Folic Acid:	11 ug
Total Fibre:	2.3 g



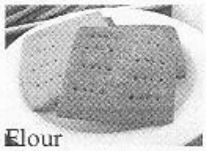
Chocolate Coated Crackers

Molding milk chocolate	11 g
Butterscotch chips	5 g
Pea hull fibre	2 g
Multigrain Cracker	2 crackers

- Place butterscotch chips and chocolate in a jar.
- Microwave for 1 min 30 sec on high.
- Mix and let sit for 1 min.
- Microwave for another 1 min. 45 sec on high.
- Stir in fibre and coat crackers.

Nutrition Facts:
Per two crackers

Calories:	120 kcal
Total Fat:	6.5 g
Saturated Fat:	3.5 g
Protein:	1 g
Carbohydrates:	15 g
Cholesterol:	3 mg
Sodium:	70 mg
Potassium:	65 mg
Folic Acid :	9 ug
Fibre :	2.1 g



Honey graham crackers

Flour	100 g
Whole wheat flour	78 g
Salt	1.5 g
Baking soda	1.5 g
Cinnamon	0.8 g
Pea hull fibre	27 g
Butter	85 g
Granulated sugar	35 g
Brown sugar	15 g
Honey, creamed	15 g
Vanilla	1.25 g
Egg	25 g
Milk	45 g

- Mix the dry ingredients together in a bowl.
- With the paddle attachment of your electric mixer, beat the cold butter until it is soft.
- Add the sugars and continue beating.
- Then add the honey, vanilla, egg and milk and beat until combined.
- Add the dry ingredients to the mixer bowl and beat until a fairly firm dough is made.
- Wrap the dough in plastic and place it in the refrigerator to chill.
- When the dough is firm enough to roll, lightly dust a countertop and a rolling pin and roll the dough to a scant ¼-inch thick.
- Preheat the oven to 350° F.
- Cut it into 3 cm x 6 cm and place them on a well-greased baking sheet with a margin of space to allow for spreading.
- Use a folk to pierce the crackers.
- Bake them at 350° F for 10 min.
- Remove them to a wire rack to cool.
- 2 crackers for 1 serving.
- Makes 25 crackers.

Nutrition Facts
Per two crackers

Calories:	120 kcal
Total Fat:	6 g
Saturated Fat:	3 g
Protein:	2 g
Carbohydrates:	17 g
Cholesterol:	25 mg
Sodium:	125 mg
Potassium:	55 mg
Folic Acid:	30 µg
Fibre:	3 g

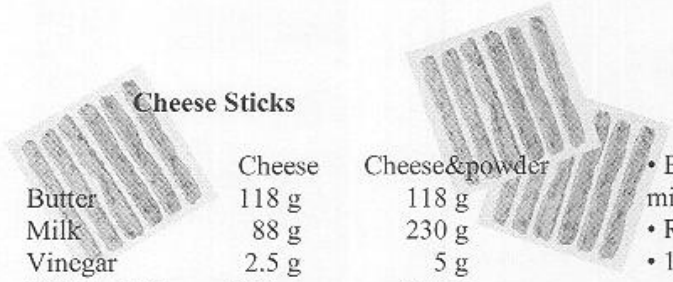
Chocolate Cheerios

Cheerios	14 g
Pea hull fibre	2 g
Molding milk chocolate	10 g
Icing Sugar	3 g

- Shake cheerios and fibre in a plastic bag.
- Place chocolate in jar.
- Microwave for 3 min on high.
- Coat Cheerios with the chocolate.
- Chill and dust with icing sugar.
- Makes one serving.

Nutrition Facts
For one serving

Calories:	120 kcal
Total Fat:	4 g
Saturated Fat:	2 g
Protein:	2.5 g
Carbohydrates:	21 g
Cholesterol:	2.5 mg
Sodium:	140 mg
Potassium:	100 mg
Folic Acid:	155 ug
Fibre:	3.5 g



Cheese Sticks

	Cheese	Cheese&powder
Butter	118 g	118 g
Milk	88 g	230 g
Vinegar	2.5 g	5 g
Baking soda	2.25 g	2.25 g
Salt	1.65 g	1.65 g
Flour	248 g	248 g
Pea hull fibre	72 g	72 g
Water	105 g	-
Cheese (shredded)	108 g	108 g
Kraft powder	-	15 g

• Mix flour and fibre.
• Work the butter into the flour with a pastry cutter. (Add shredded cheese.)
• Stir vinegar, baking soda and salt into milk.
• Let rest for 2 min. (Stir Kraft powder into milk.)
• Add this to the butter- flour mixture.
• Form dough, roll out and make strings using a pasta machine (thinness 4).
• Bake them for 7 min. at 375° F, then fan min at 175° F.
• Remove them to a wire rack to cool.
• 15 g for 1 serving.

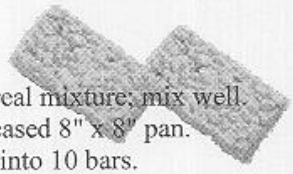
Nutrition Facts
Per 15 gram serving

Calories:	80 kcal
Total Fat:	5 g
Saturated Fat:	2.5 g
Protein:	2 g
Carbohydrates:	9 g
Cholesterol:	13 mg
Sodium:	105 mg
Potassium:	40 mg
Folic Acid:	25 ug
Fibre:	2.4 g

Rice Crispy – Cranberry & Coconut

Rice crispy	40 g
Oatmeal, quick cooking	70 g
Cranberry raisins	15 g
Coconut, sweetened long	5 g
Pea hull fibre	20 g
Butter	62 g
White sugar	82 g
White corn syrup	34 g
Honey	15 g
Vanilla	2.5 g

• Shake rice crispy, oatmeal, cranberry, raisins, coconut and fibre in a plastic bag.
• Combine butter, sugar, syrup and honey and cook at 230° F.
• Remove from heat.
• Add vanilla.
• Pour over cereal mixture; mix well.
• Press into greased 8" x 8" pan.
• Cool and cut into 10 bars.
• 1 bar for 1 serving.



Nutrition Facts
Per bar

Calories:	140 kcal
Total Fat:	6 g
Saturated Fat:	3 g
Protein:	2 g
Carbohydrates:	24 g
Cholesterol:	13 mg
Sodium:	95 mg
Potassium:	45 mg
Folic Acid:	35 ug
Fibre:	2.5 g

APPENDIX 5

Questionnaires

5.1 Pre-Study Questionnaire

The Effect of Fibre Fortification on Stool Frequency
In Children with a History of Constipation

Your Name:_____Child's Name:_____

This questionnaire was designed to collect information on the medical history of your child that is relevant to his/her participation in this study. There will also be questions about the medications and supplements that your child is currently taking. Information that you provide will be kept confidential.

1. Has your child experienced constipation in the last 12 months? The Canadian Paediatric Society defines constipation as "bowel movements that happen less often than usual, are hard and dry, and/or are difficult or painful to pass".
   - ☐ Yes
   - ☐ No
   - ☐ Not sure

2. Does your child have a known allergy to milk or milk products such as yogurt?
   - ☐ Yes
   - ☐ No
   - ☐ Not sure

3. Does your child have a known allergy to peas?
   - ☐ Yes
   - ☐ No
   - ☐ Not sure

4. Has your child ever been diagnosed with celiac disease?
   - ☐ Yes
   - ☐ No
   - ☐ Not sure

5. Has your child had an enema for constipation in the last week?
   - ☐ Yes
   - ☐ No
   - ☐ Not sure

6. Has your child experienced stool leakage in the last month?
   - ☐ Yes
   - ☐ No
   - ☐ Not sure

7. Please indicate if your child has been diagnosed with any of the following:

   - ☐ Hirschsprung disease
   - ☐ Neurological abnormality such as seizure disorder
   - ☐ Kidney disease
   - ☐ Mental deficiency
   - ☐ Psychiatric illness
   - ☐ Low calcium blood levels
   - ☐ High potassium blood levels

8. Has your child ever had surgery on his or her intestines?
   - ☐ Yes
   - ☐ No
   - ☐ Not sure

9. Please list the medications that your child is currently taking and the dosage.

_____
_____
_____
_____
_____

10. Please list any supplements such as herbal medications, vitamins and minerals that your child is currently taking.

_____
_____
_____
_____
_____

5.2 Cross-Over Questionnaire

The Effect of Fibre Fortification on Stool Frequency
In Children with a History of Constipation

Your Name:_____Child's Name:_____

This questionnaire was designed to collect information about how your child is doing at this point in the study. The information that you provide will be kept confidential.

1. Do you think your child's stool frequency has changed since the start of the study?
   - ☐ Yes
   - ☐ No
   - ☐ Not sure

   If yes, has your child's stool frequency:
   - ☐ Increased
   - ☐ Decreased

2. Do you think that your child's abdominal pain has changed since the start of the study?
   - ☐ Yes
   - ☐ No
   - ☐ Not sure
   - ☐ Not applicable

   If yes, has your child's abdominal pain:
   - ☐ Increased
   - ☐ Decreased

3. How often, on average, does your child drink the yogurt or milk drink provided?
   - ☐ None
   - ☐ Less than one serving per day
   - ☐ One serving per day
   - ☐ More than one serving per day

4. How often, on average, does your child eat the snack foods provided?
   - ☐ None
   - ☐ Less than one serving per day
   - ☐ One serving per day
   - ☐ Two servings per day
   - ☐ More than two servings per day

5. Have there been any changes in the way your child feels physically since the start of the study? He/she is feeling…
    - ☐ A lot better
    - ☐ A little better
    - ☐ About the same
    - ☐ A little worse
    - ☐ A lot worse

6. Have there been any changes in the way your child feels emotionally since the start of the study? He/she is feeling…
    - ☐ A lot better
    - ☐ A little better
    - ☐ About the same
    - ☐ A little worse
    - ☐ A lot worse

7. How has your child been getting along with other children since the start of the study? He/she is getting along with other children…
    - ☐ A lot better
    - ☐ A little better
    - ☐ About the same
    - ☐ A little worse
    - ☐ A lot worse

8. Do you have any comments, questions or concerns about any part of the study to date?

_____
_____
_____
_____
_____
_____

5.3 Post-Study Questionnaire

The Effect of Fibre Fortification on Stool Frequency
In Children with a History of Constipation

Your Name:_____ Child's Name:_____

This questionnaire was designed to collect information about how your child is doing since the mid-point of the study (about three weeks ago). The information that you provide will be kept confidential.

1. Do you think your child's stool frequency has changed since the mid-point of the study?
   - ☐ Yes
   - ☐ No
   - ☐ Not sure

   If yes, has your child's stool frequency:
   - ☐ Increased
   - ☐ Decreased

2. Do you think that your child's abdominal pain has changed since the mid-point of the study?
   - ☐ Yes
   - ☐ No
   - ☐ Not sure
   - ☐ Not applicable

   If yes, has your child's abdominal pain:
   - ☐ Increased
   - ☐ Decreased

3. How often, on average, does your child drink the yogurt or milk drink provided?
   - ☐ None
   - ☐ Less than one serving per day
   - ☐ One serving per day
   - ☐ More than one serving per day

4. How often, on average, does your child eat the snack foods provided?
   - ☐ None
   - ☐ Less than one serving per day
   - ☐ One serving per day
   - ☐ Two servings per day
   - ☐ More than two servings per day

5. Have there been any changes in the way your child feels physically since the mid-point of the study? He/she is feeling…
    - ☐ A lot better
    - ☐ A little better
    - ☐ About the same
    - ☐ A little worse
    - ☐ A lot worse

6. Have there been any changes in the way your child feels emotionally since the mid-point of the study? He/she is feeling…
    - ☐ A lot better
    - ☐ A little better
    - ☐ About the same
    - ☐ A little worse
    - ☐ A lot worse

7. How has your child been getting along with other children since the mid-point of the study? He/she is getting along with other children…
    - ☐ A lot better
    - ☐ A little better
    - ☐ About the same
    - ☐ A little worse
    - ☐ A lot worse

8. Do you have any comments, questions or concerns about any part of the study?

_____
_____
_____
_____
_____
_____

APPENDIX 6

Study Materials

6.1 Study Diary

My Study Diary

Name _____

Date							
Put a check (✓) in the box if you had these foods/drinks today *Your goal is to have one yogurt drink plus two other snack foods every day*							
Yogurt Drink							
Crackers							
Cookies							
Granola bar							
Puffed wheat cake							
Other							
Stools – describe stools when present							
Frequency (# of stools/day)							
Description (Rate 1-7, see back page of diary)							
Stomach Pain							
0=None,1=a little, 2=moderate,3=a lot							

6.2 Stool Form Rating Scale

Stool Form Rating Scale

- 1= separate hard lumps like nuts,
- 2 = sausage shaped but lumpy,
- 3 = like a sausage but with cracks on surface,
- 4 = like a sausage, smooth and soft,
- 5 = soft blobs with clear-cut edges,
- 6 = fluffy pieces with ragged edges,
- 7 =watery, solid pieces.